Probably there are not that many inventions in the world that have the same powerful reason-why foundation as the electromagnetic DETA-therapy.

The diagnostic and therapeutic DETA devices had undergone hundreds of tests in tens of prophylactic and medical institutions in Russia, Kyrgyzstan, Kazakhstan, Ukraine, Israel, and Bulgaria where proved to be an extremely effective tool in treating wide variety of diseases.

[Stamp]

APPROVED

by the Rector of State Educational Institution of Higher Professional Training “Nizhniy Novgorod State Medical Academy”

Professor Shakhov B.E. [Signature]

September 4, 2009

CLINICAL TRIAL PROTOCOL ON

THE DETA-AP EFFICACY IN TREATMENT OF ACUTE AND CHRONIC PID IN GYNECOLOGY

2009

Basis for Undertaking the Study: Agreement on Conducting Post-Registration Approbation, November 7, 2008.

Study Goal: To assess the efficacy of the DETA-AP device in therapy of patients with PID associated with chlamydia, mycoplasma, ureaplasma, CMV-infections, herpetic infection, and HPV-infection.

Study Type: Open-label, nonrandomized, comparative.

Study Objectives:

1. To determine clinical efficacy of traditional antibacterial and antiviral therapy of patients with PID associated with chlamydia, mycoplasma, ureaplasma, CMV-infections, herpetic infection, and HPV infection.

2. To study clinical efficacy of using the DETA-AP device as a complementary method of the traditional antibacterial and antiviral therapy of patients with PID associated with chlamydia, mycoplasma, ureaplasma, CMV-infections, herpetic infection, and HPV infection.

3. To determine clinical efficacy of using the DETA-AP device as monotherapy in treatment of patients with PID associated with chlamydia, mycoplasma, ureaplasma, CMV-infections, herpetic infection, and HPV infection.

4. To assess safety of using the DETA-AP device in treatment of the abovementioned diseases.

Investigational Plan:

The subjects of the investigation were women of reproductive age (18-42 years of age) provided with the outpatient care at the Prenatal Clinic#10 of Public Health Care Facility "Maternity Clinic #4". Subjects were selected based on the distinguished inclusion criteria.

Inclusion Criteria: Subjects included into the study were women acquired acute or chronic PID associated with chlamydia, mycoplasma, ureaplasma, CMV-infections, herpetic infections, and HPV infections, suffering from chronic and acute inflammatory diseases of feminine reproductive system. The diseases were confirmed by EIA blood tests and PCR tests.

For medical examination and treatment, patient volunteered informed content was obtained according to the Order No. 163 (OCT 91500.14.0001-2002) of Ministry of Healthcare of the Russian Federation. The investigation was agreed with local Ethic Committee of Government-Owned Healthcare Institution "Nizhniy Novgorod Regional Clinical Hospital" named after N.A. Semashko.

Study Location and Period: Prenatal Clinic#10 of Public Health Care Facility "Maternity Clinic #4" in Nizhniy Novgorod; duration period from November 7, 2008 to December 1, 2009.

The study was supplied with:

1. Three (3) DETA-AP devices manufactured by LLC Scientific Development and Production Enterprise "ELIS", Moscow. The device software is designed to conduct antiparasitic electromagnetic wave therapy.

2. The DETA-AP devices are authorized for use in medical practices (Product License by Federal Service on Surveillance in Healthcare and Social Development of the Russian Federation No. ФС 022 a 1710/4625-06, December 22, 2011).

3. Operation Manual for the DETA-AP devices.

4. Guidelines of Using the DETA devices. Methodology for diagnostics and treatment is covered by the Patent No. 2000114578 from March 20, 2003, legitimately used by LLC Scientific Development and Production Enterprise "ELIS".

Study Results:

During the investigation on clinical efficacy of different methods of treatment of PID caused by chlamydia, mycoplasma, ureaplasma, cytomegalovirus infections, herpetic infections, and HPV infections, 45 female patients, aged 18 to 42 (mean age 29.3 ±1.1), were enrolled. Diagnoses were clinically established and confirmed with the data of enzyme immunoassay testing and PCR method of finding DNA-paragraphs of causative agents.

The primary group was divided into two subgroups: the first subgroup (N1) was treated with the combination of medicated and bioresonant therapies; the second subgroup (N2) was treated by only using the DETA-AP device.

Control group (N3), that only received medicated therapy, consisted of total 55 women, aged 18 to 42 (mean age 26.3±1.2).

The study groups matched on age, clinical entity, and primary disease severity.

Treatment Procedure. Before the treatment, the DETA device was prepared for work according to the instructions of the operation manual of equipment. These manual instructions were also followed when turn power on and off. The device was located in the projection of a patient hotbed of a disease during the procedure. Procedure duration depended on an individual set of programs; and the average duration of the treatment was 40-60 minutes. All patients of the primary group had 3 sessions of bioresonant therapy every other day and 3 sessions of detoxification bioresonant therapy.

To evaluate the efficacy of treatment with the applied methods, patients were clinically examined once in two days by assessing their general state of health and thermometry. Before and

after the complete therapy, there were conducted a special gynecologic examination, pelvic ultrasound, complete blood analysis, including leukogram, blood-sedimentation test, leukocytical intoxication index. The vaginal microbiocenosis was tested before and after the treatment with the method of light microscopy and bacteriological study.

Clinical observation of patients proved that using the DETA-AP device as a monotherapy and in combination with medicated therapy had more profound positive therapeutic results comparing to the standard antibacterial and antiviral treatment. Treatment efficacy was verified with normalization of temperature, measurements of general blood analysis, and local state. Elimination of pain syndrome of the primary group patients occurred on the second day, what is three times faster than in the control group.

Table 1 presents clinical characteristics of the observation groups and the results of different methods of treatment of pelvic inflammatory disease.

Table 1.

Diagnosis	Number of patients			Average Treatment Duration for Combined Pharmaceutic and Bioresonant Therapies	Average Treatment Duration for Monotherapy with DETA-AP device	Average Treatment Duration for Traditional Pharmaceutical Treatment
	N1	N2	N3			
Chlamydiosis	6	2	10	12,2±1,4	3±0	14,53±1,7
Mycoplasmosis	3	2	9	7,23±1,1	3±0	8=bI ,3
Ureaplasmosis	6	2	10	8,93±0,9	3±0	9,33±1,1
Cytomegalovirus	6	3	8	10,73±1,2	3±0	12,23±1,5
HPV infection	5	3	10	14,43±1,3	3±0	15,93±1,3
Herpetic infections	4	3	8	21,3±2,7	3±0	24,53±3,0

Acceptability. It should be noted that therapy with the DETA-AP device is convenient and well tolerated by patients; there are also no general or local side effects of treating PID caused by chlamydia, mycoplasma, ureaplasma, cytomegalovirus, herpetic, and human papillomavirus infections. This therapy did not negatively impact the associated somatic pathologic behavior. Moreover, the application of restorative frequencies, that are integrated in the DETA device, for the antiparasitic treatment provides faster recovery of anatomy and functionality of the target affected organs.

Conclusions.

1. Traditional antibacterial and antiviral therapy proved to be less effective in treatment of PID caused by chlamydia, mycoplasma, ureaplasma, CMV-infection, herpetic infections, and HPV-infection (60-65%).
2. For the treatment of PID caused by chlamydia, mycoplasma, ureaplasma, CMV-infection, herpetic infections, and HPV-infection, the high clinical efficacy of the DETA device was revealed: 87-92% when combined with medicated method of treatment, and 85% when used as monotherapy.
3. There are no contraindications found for usage of the DETA-AP device to treat patients' PID associated with chlamydia, mycoplasma, ureaplasma, CMV-infection, herpetic infections, and HPV-infection.
4. The usage of the DETA-AP device is possible in a hospital, on an outpatient basis, and domiciliary.

[Stamp]

APPROVED

by the Chief Doctor of MPTF Clinical Maternity Hospital No.4

Urban District of Ufa, Republic of Bashkortostan

Kamalov E.M. [Signature]

May 20, 2009

CLINICAL TRIAL PROTOCOL ON

THE DETA-AP EFFICACY FOR TREATMENT

2009

Basis for Undertaking the Study: Agreement on Conducting Post-Authorization Clinical Approbation, March 28, 2009.

Study Goal: To assess the possibilities of treatment of gynecological disorders associated with genitourinary infections – including chlamydiosis, ureaplasmosis, mycoplasmosis, gardnerellosis, candidiasis, cytomegalovirus, herpetic and toxoplasma infections – using the DETA device manufactured by the LLC Scientific Development and Production Enterprise "ELIS" in medical practices in the Russian Federation.

Study Type: Open-label, nonrandomized, reference-controlled.

Study Objectives:

1. To determine clinical efficacy of the DETA device as monotherapy during delitescent carrier state and acute exacerbation of chronic genitourinary infections.
2. To study clinical efficacy of using the DETA device as a part of combined therapy of

acute inflammatory genital infections associated with para-venereal infections.

3. To assess safety of using the DETA device in treatment of the abovementioned diseases.

Investigational Plan:

Women of reproductive age (18-42 years of age) were enrolled into the study. All subjects were hospitalized in Gynecology Department of the Municipal Perinatal Center.

Subjects were selected based on the distinguished inclusion criteria.

Inclusion Criteria: The subjects included into the study were female patients with chlamydiosis, ureaplasmosis, mycoplasmosis, gardnerellosis, candidiasis, cytomegalovirus, herpetic and toxoplasma infections that had been confirmed by conducting the EIA blood tests and the PCR tests, and those suffering chronic and acute inflammatory diseases of feminine reproductive system and having anamnesis records of recurrent miscarriage and infertility.

For medical examination and treatment, patient volunteered informed content was obtained according to the Order No. 163 (OCT 91500.14.0001-2002) of Ministry of Healthcare of the Russian Federation. The study was agreed with the Ethic Committee.

Study Location and Period: Gynecology Department of MPTF Maternity Clinic #4 in Ufa.

The study was supplied with:

1. Three (3) DETA-AP devices and three (3) DETA-RITM devices manufactured by LLC Scientific Development and Production Enterprise “ELIS”, Moscow. The device software is designed to conduct antiparasitic electromagnetic wave therapy.
2. The DETA-AP devices are authorized for use in medical practices (Product License by Federal Service on Surveillance in Healthcare and Social Development of the Russian Federation No. ФС 022 a 1710/4625-06, December 22, 2011).
3. Operation Manuals for the DETA devices.
4. Guidelines of using the DETA devices.

Methodology for diagnostics and treatment is covered by the Patent No. 2000114578 from March 20, 2003, legitimately used by LLC Scientific Development and Production Enterprise “ELIS”.

Study Results:

For the study on clinical efficacy of different treatment methods of gynecologic diseases, including chlamydiosis, ureaplasmosis, mycoplasmosis, gardnerellosis, candidiasis, cytomegalovirus, herpetic and toxoplasma infections, 46 female patients, aged 18 to 42, were enrolled (mean age 27.4±1.1).

Diagnoses were clinically established and confirmed with the data of enzyme immunoassay testing and PCR method of finding DNA-paragraphs of causative agents.

The primary group was divided into two subgroups: the 1st subgroup received the DETA device therapy; the 2nd subgroup received combined medicated and bioresonant therapy.

The control group (that had only medicated therapy) consisted of 55 female patients, aged 18 to 42 (mean age 26.3±1.2).

The study groups matched on age, clinical entity, and primary disease severity.

Treatment Procedure. Before the treatment, the DETA device was prepared for work according to the instructions of the operation manual of the equipment. These manual instructions were also used to turn power on and off. The device was located in the projection of a patient hotbed of a disease during the procedure. Procedure duration depended on an individual set of programs; and the average duration of the treatment was 40-50 minutes. The frequency was 1-2 procedures per day, depending on acceptability; the complete course duration was 5 to 10 days.

The necessity of medicated therapy was determined by the severity conditions of the patients. If significant symptoms of intoxication, the female patients with post-delivery and post-operation endometritises and infiltrations received detoxification fluid and anti-bacterial therapy. The bioresonant monotherapy was only conducted for patients with moderate symptoms of intoxication, mild and moderate severity of a disease.

Treatment efficacy of the methods applied was assesses by everyday clinical examinations, including assessment of general state of health and thermometry, specific gynecologic examination; once in 3 days, there were ultrasound examinations and clinical blood test determining leukogram, blood-sedimentation, leukocytical intoxication index. The vaginal

microbiocenosis was examined before and after the treatment with the method of light microscopy and bacteriological test.

Clinical observations showed: patients had more distinct positive therapeutic results when receiving monotherapy using the DETA device or combined bioresonant and medicated therapy, comparing to the control group, that was given antibiotics, fluid therapy and anti-inflammatory therapy.

The treatment efficacy was shown in the decrease of intoxication symptoms (normalization of temperature, values of full blood tests, local state). Liquidation of pain syndrome of the primary group patients occurred on the second day what is 3 times faster than in the control group.

Table 1 demonstrates clinical characteristics of the study groups and impact of different methods of treatment of pelvic inflammatory diseases.

Acceptability. It should be noted that the DETA device therapy is convenient and well tolerated by patients; there are also no general or local side effects of treating gynecologic diseases associated with genitourinary infections such as chlamydiosis, ureaplasmosis, mycoplasmosis, gardnerellosis, candidiasis, cytomegalovirus, herpetic and toxoplasma infections

Therapy had no negative impact on the development of associated somatic pathologies of the observed patients. Moreover, combined application of DETA-RITM and restorative frequencies, integrated into anti-parasitic programs of DETA-AP, supports faster recovery of the anatomy and functionality of the target affected organs.

Conclusions.

1. By its functionality and operational capability, the DETA device (with the “AP” software) entirely meets the requirements of medical practices of treatment of gynecologic diseases.
2. Using the DETA device as monotherapy or in combination with medicated method proved to be more clinically efficient than the traditional methods of treatment.
3. There are no contraindications found of using the DETA device for treatment of patients with acute and chronic genitourinary infections.
4. The usage of the DETA device is possible in a hospital, on an outpatient basis, and domiciliary.

Table 1.

Diagnosis	Number of patients		Average duration of traditional medicated therapy in the control group, in days	Average duration of treatment using the DETA device in the primary group, in days	Average duration of treatment using combined DETA device and medicated therapy in the primary group, in days
	Primary group	Control group			
Post-delivery metroendometritis caused by:	N=14	N=25	10,3±0,8	Because of severity of patients' diseases, the treatment included medicated therapy; the only use of the DETA device was not possible.	5,3±0,2
- Chlamidiosis	5	7	12,3 ±0,4		7,3 ±0,10
- Ureaplasmosis	7	11	8,3 ±0,3		6,1 ±0,09
- Mycolplasmosis	7	13	9,2 ±0,4		6,8 ±0,3
- CMV-infection	11	21	10,7 ±0,6		5,3 ±0,05
- HSV	11	22	12,3±0,5		5,7±0,1
Acute exacerbation of endometritis and salpingitis caused by:	N=16	N=15	9,3±0,4	6,3±0,1	6,0±0,2
			10,3 ±0,2	6,7 ±0,2	6,2 ±0,2
- Chlamidiosis	8	9	8,3 ±0,3	6,3 ±0,3	6,2 ±0,1
- Ureaplasmosis	7	8	7,2 ±0,4	6,1 ±0,1 •	6,1 ±0,3
- Mycolplasmosis	9	7	14,7 ±0,1	7,2 ±0,1	5,7±0,1
- CMV-infection	14	11	13,3±0,2	7,1 ±0,1	5,9±0,2
- HSV	12	11			
Colpitis and cervicitis caused by:	N=16	N=15	13,3 ±0,7	6,1 ±0,1	There were no patients treated with combined therapy as it was
- Chlamidiosis	9	8	10,1 ±0,4	6,4 ±0,2	

- Ureaplasmosis	7	7	12,3 ±0,1	6,2 ±0,2	needless.
- Mycolplasmosis	7	9	9,2 ±0,4	6,1 ±0,1	
- CMV-infection	13	11	14,7 ±0,6	7,1 ±0,1	
- HSV	11	12	13,3 ±0,5	7,2 ±0,1	

Stamping

Recommendations.

Principal Investigator /Signature/ Candidate of Medicine ***Saubanova T.V.***

Chief Doctor of MPTF Clinical /Signature/ Candidate of Medicine ***Kamalov E.M.***

Maternity Hospital No.4

[Stamp]

APPROVED

by the Chied Doctor of Emergency Hospital

Ishmukhametov G. S. [Signature]

May 6, 2010

CLINICAL TRIAL PROTOCOL ON

DETA-13 EFFICACY FOR TREATMENT

2010

Basis for Undertaking the Study: Agreement on Conducting Post-Authorization Clinical Approbation.

Study Goal: To assess the efficacy of the DETA-13 device, manufactured by LLC Scientific Development and Production Enterprise “ELIS”, in treatment of gynecological diseases associated with genitourinary infections – including chlamydiosis, ureaplasmosis, mycoplasmosis, nonspecific acute and chronic hysteropathies, and also for treating post-surgical patients, in medical practices in the Russian Federation.

Study Type: Open-label, nonrandomized, reference-controlled.

Study Objectives:

1. To assess clinical efficacy of using the DETA-13 device, as monotherapy and combined with the traditional therapy methods, for the treatment of acute type and acute exacerbation of genitourinary infection
2. To study clinical efficacy of using the DETA-13 device as a part of combined post-surgical treatment.
3. To assess safety of using the DETA-13 device in treatment of the abovementioned diseases.

Investigational Plan:

Women of reproductive age (18-42 years of age) were enrolled into the study. All subjects were hospitalized in the Gynecologic Department of the Emergency Hospital. They were selected based on the distinguished inclusion criteria.

Inclusion Criteria: Subjects included into the study were female patients with chlamydiosis, ureaplasmosis, mycoplasmosis, infections of nonspecific causation, that had been confirmed by conducting EIA blood tests and PCR tests, and suffering chronic and acute inflammatory diseases of feminine reproductive system; including those having surgery for pelvic organs.

For medical examination and treatment, patient volunteered informed content was obtained according to the Order No. 163 (OCT 91500.14.0001-2002) of Ministry of Healthcare of the Russian Federation. The study was agreed with the Ethic Committee.

Study Location and Period: Gynecology Department of the Emergency Hospital in Ufa.

The study was supplied with:

5. Two (2) DETA-AP-13 and two (2) DETA-RITM-13 devices, manufactured by LLC Scientific Development and Production Enterprise "ELIS", Moscow. The device software is designed to conduct antiparasitic and recovery electromagnetic wave therapy.
6. The DETA-13 devices are authorized for use in medical practices (Product License by Federal Service on Surveillance in Healthcare and Social Development of the Russian Federation No. ФС 022 a 1710/4625-06, December 22, 2011).
7. Operation Manuals for the DETA-13 devices.
8. Guidelines of using the DETA-13 devices.

Methodology for diagnostics and treatment is covered by the Patent No. 2000114578 from March 20, 2003, legitimately used by LLC Scientific Development and Production Enterprise "ELIS".

Study Results:

During the period of January 10, 2010 to May 5, 2010, the study on clinical efficacy of different correction methods of various gynecologic diseases associated with genitourinary infections, such as chlamydiosis, ureaplasmosis, mycoplasmosis, and nonspecific inflammatory diseases, was accomplished for 28 female patients, aged 18-42 (mean age 27.3±1.0).

Diagnosis of the diseases were established clinically and were confirmed with the data of enzyme immunoassay testing and PCR method of finding DNA-paragraphs of causative agents taken in the lower genitourinary tract.

The primary group was divided into two subgroups: the 1st subgroup received only the DETA-13 therapy; and the 2nd subgroup received combination of medicated and bioresonant therapies.

The control group – that only received medicated therapy – consisted of 35 female patients, aged 18 to 42 (mean age 27.8±1.1).

The study groups matched on age, clinical entity, and primary disease severity.

Treatment Procedure. Before the treatment, the DETA-13 device was prepared for work according to the instructions of the operation manual of the equipment. These manual instructions were also used when turning power on and off. The device was located in the projection of a patient hotbed of a disease during the procedure. Procedure duration depended on an individual set of programs and lasted from 50 to 240 minutes, at average of 90-120 minutes. The frequency was 1-2 procedures per day, depending on acceptability; the complete course duration was 5 to 10 days.

The necessity of the medicated therapy in the primary group was determined by severity conditions of the patients. If significant symptoms of intoxication, the female patients, suffering acute virulent inflammatory diseases, received detoxification fluid and anti-bacterial therapy.

The bioresonant monotherapy was conducted for patients with moderate symptoms of intoxication, mild and moderate severity of a disease.

Treatment efficacy of the methods applied was assessed by everyday clinical examinations, including assessment of general state of health, thermometry, and specific gynecologic examination. Once in 3 days, there were ultrasound examination, clinical blood test determining leukogram, blood-sedimentation, and leukocytical intoxication index. The vaginal microbiocenosis was examined before and after the treatment with the method of light microscopy and bacteriological test. In 1.5-2 months after the treatment, its efficacy was proved with PCR and EIA methods, and bacteriologic tests.

Clinical observations demonstrated: patients had more distinct positive therapeutic results when receiving monotherapy using the DETA-13 device or combined bioresonant and medicated therapy than the control group, that was given antibiotics, fluid therapy and anti-inflammatory therapy.

Treatment efficacy was shown in the decrease of intoxication symptoms (normalization of temperature, values of full blood tests, and local state). Liquidation of pain syndrome of the primary group patients occurred on the second or third day what is 2 times faster than in the control group.

The therapy is well-tolerated as it has no negative impact on a general state of patient and does not cause intense intoxication that needs medically induced correction.

Table 1 demonstrates clinical characteristics of the study groups and impact of different methods of treating pelvic inflammatory diseases.

Acceptability. It should be noted that therapy with the DETA-13 device is convenient and well tolerated by patients; there are also no general or local side effects of treating gynecologic diseases associated with genitourinary infections such as chlamydiosis, ureaplasmosis, mycoplasmosis, and nonspecific infections.

Therapy had no negative impact and contributed to faster recovery of the anatomy and functionality of the target affected organs of the patients.

Treatment of the functional ovarian cyst with the help of the DETA-13 devices was 89 percent efficient. Treatment duration was 5 to 7 days.

It should also be mentioned that, the DETA-13 devices were the effective tool in the treatment of the post-surgery patients. Used software programs are ‘Surgury-Pain’, ‘Acute Pain’, ‘Detoxification’, ‘GIT Regulation’, and ‘Blood Circulation’. Milder post-surgical causes were observed: less pain-killing medications were needed; the patients had milder anesthesia recovery; there were no post-surgery complications.

Totally treated post-surgery patients equaled 30; the control group consisted of 20 patients. Treatment order of pain-killing medications lasted for 3-5 days for the control group, and for 1-2 days for the primary group.

Two women with long-lasting amenorrhea had maturation of follicles; their treatment lasted for 10 days. After stopping the application of the devices, the hot flashes started. The further software development is needed.

Conclusions.

1. By their functional and operational qualities, the DETA-AP-13 and DETA-RITM-13 devices (with the software) completely meet the requirements of medical practices in the field of the treatment of gynecologic diseases.
2. Using of the DETA-13 devices as monotherapy and together with medicated therapy has proven to have higher clinical effects in the treatment of chronic and acute inflammatory

diseases of pelvic organs associated with genitourinary infections, than the traditional methods of treatment. It was also noticed high clinic effect of treating post-surgery patients.

3. No contradictions for using the DETA-13 device were found out.
4. The usage of the DETA-13 device is possible in a hospital, in the outpatient facility, and at home.

Table 1.

Diagnosis	Number of patients		Average Duration of traditional medicated therapy in the control group, in days	Average Duration of treatment using DETA device in the primary group, in days	Average Duration of treatment using combined the DETA device and medicated therapy in the primary group, in days
	Primary group	Control group			
Exacerbation of chronic endometritis and salpingo-oophoritis caused by:	N=28	N=35	9,3±0,2	6,4±0,1	6,1 ±0,2 7,2 ±0,2
• Chlamediosis	3	5	14,3 ±0,3	7,9 ±0,2	6,3 ±0,1
• Ureaplasmosis	7	4	10,3 ±0,2	6,5 ±0,2	6,4 ±0,3
• Mycoplasmosis	6	8	10,2 ±0,1	5,4 ±0,2	5,7±0,1
• Nonspecific microflora	12	18	14,3 ±0,3	5,0 ±0,1	5,9 ±0,2

Stamping

Recommendations.

Chief Doctor	[Signature]	G.S. Ishmukhametov
Principal Investigator	[Signature]	N.I. Sablina

[Stamp]

APPROVED

Pro-rector for Research

State Educational Institution of Higher Professional Training

Bashkir State Medical University of

Federal Service of Surveillance in Healthcare

Candidate of Medicine, Professor

E.K. Alekhin [Signature]

2009

CLINICAL TRIAL PROTOCOL ON

THE DETA DEVICE EFFICACY FOR TREATMENT

2010

Basis for Undertaking the Study: Agreement on Conducting Post-Authorization Clinical Approbation, March 28, 2009.

Study Goal: 1. To study the capability of the DETA-AP device, manufactured by the LLC Scientific Development and Production Enterprise “ELIS”, in treating giardiasis of adults and children in medical practiced in the Russian Federation.

2. To study the capability of the combined employment of the DETA-AP and DETA-RITM devices, manufactured by LLC Scientific Development and Production Enterprise “ELIS”, in treating giardiasis of adults and children in medical practiced in the Russian Federation.

Study Type: Open-label, nonrandomized, reference-controlled.

Study Objectives:

1. To determine the clinical efficacy of using the DETA-AP device as monotherapy when treating acute intestinal giardiasis.
2. To study clinical efficacy of using the DETA-AP device as a part of combined treatment of acute giardiasis.
3. To study clinical efficacy of using the DETA-AP device for treating hepatobiliary form of chronic giardiasis.
4. To study clinical efficacy of using the DETA-AP and DETA-RITM devices as a part of combined treatment of hepatobiliary form of chronic giardiasis.
5. To study clinical efficacy of using the DETA-AP device for treating asthenoneurotic form of chronic giardiasis.
6. To study clinical efficacy of using the DETA-AP and DETA-RITM devices as a part of combined treatment asthenoneurotic form of chronic giardiasis.
7. To assess safety of using the DETA devices for the treatment of giardiasis.

Investigational Plan:

48 people were enrolled into the study. They were selected based on the distinguished inclusion criteria.

Inclusion Criteria: the study included 48 people whose diagnoses were confirmed with laboratory bacterioscopical and immunological tests. For medical examination and treatment, patient volunteered informed content was obtained according to the Order No. 163 (OCT 91500.14.0001-2002) of Ministry of Healthcare of the Russian Federation.

Study Location and Time: the study was conducted in the office of the outpatient clinic and domiciliary.

The study was supplied with:

1. One (1) DETA-AP device, manufactured by LLC Scientific Development and Production Enterprise “ELIS”, Moscow. The device software is designed to conduct antiparasitic electromagnetic wave therapy.

2. One (1) DETA-RITM device, manufactured by LLC Scientific Development and Production Enterprise “ELIS”, Moscow. The device software is designed for:
    - normalization of the gastrointestinal functions and immune system of patients with hepatobiliary form of chronic giardiasis;
    - normalization of the functions of nervous and immune systems of patients with asthenoneurotic form of chronic giardiasis.
3. The DETA-AP device is authorized for use in medical practices (Product License by Federal Service on Surveillance in Healthcare and Social Development of the Russian Federation No. ФСР 2009/05641, September 4, 2009).
4. The DETA-RITM device is authorized for use in medical practices (Product License by Federal Service on Surveillance in Healthcare and Social Development of the Russian Federation No. ФСР 2009/05641, September 4, 2009).
5. Operation Manual for the DETA-AP device.
6. Operation Manual for the DETA-RITM device.
7. Guidelines of using the DETA-AP-13 devices/ Methodology for diagnostics and treatment is covered by the Patent No. 2000114578 from March 20, 2003, legitimately used by LLC Scientific Development and Production Enterprise “ELIS”.

Study Results:

The study on the clinical efficacy on the different methods of treatment of giardiasis included 48 patients (8 men and 20 women, aged 22 to 65; and 20 children, aged 1.5 to 15). The diagnosis of giardiasis was clinically proven with the data of bacteriologic and immunoassay testing.

The control group that only received medicated treatment included:

- 20 people (5 men and 5 women, aged 25 to 55; and 10 children, aged 3 to 10) with acute intestinal giardiasis;
- 20 people (4 men and 6 women, aged 25 to 55; and 10 children, aged 3 to 10) with hepatobiliary form of chronic giardiasis;
- 20 people (4 men and 6 women, aged 25 to 55; and 10 children, aged 3 to 10) with asthenoneurotic form of chronic giardiasis.

The study groups matched on age, clinical entity, severity of the primary disease, and evidences of clinical implications of giardiasis. For all clinical forms of giardiasis, chosen patients

had:

1) acute intestinal giardiasis;
2) hepatobiliary form of chronic giardiasis;
3) asthenoneurotic form of chronic giardiasis.

Treatment Procedure. Before the treatment, the DETA-AP and DETA-RITM devices were prepared for work according to the instructions of the operation manual of the equipment. These manual instructions were also followed to turn power on and off. The device was located in the radius of 20-30 centimeters from the epigastric region.

The procedure duration was 1320 seconds; the frequency of application the DETA-AP device was 1 procedure per day.

1) The treatment of patients with acute intestinal giardiasis lasted for 5-7 days (7 days for children) and consisted of:

- Everyday procedures or 1-2 days of break followed by 'Drainage' program setup for adults;
- The 3 days of procedures in a row, 2 days of break, and 4 days of procedures in a row followed by 'Drainage' program setup (2,400 seconds) for children.

2) The treatment of patients with hepatobiliary form of chronic giardiasis lasted for 10-14 days followed by 'Drainage' program setup (2,400 seconds).
3) The treatment of patients with asthenoneurotic form of chronic giardiasis lasted for 10-14 days followed by 'Drainage' program setup (2,400 seconds).

Durations of the procedures with the DETA-RITM device for the treatment of chronic giardiasis depended on the time of the included programs:

- For hepatobiliary form: 'Abdominal Pain' (2,400 seconds); 'Immune System' (2,400 seconds); number of the procedures – 10-14;
- For asthenoneurotic form: 'Angioneurosis' (2,400 seconds); 'Immune System' (2,400 seconds); number of the procedures – 10-14.

Treatment efficacy of the different applied methods of correction of giardiasis was assessed by everyday clinical examinations, including assessment of general state of health, and:

- For acute intestinal giardiasis: presence of skin pallor, flatulency, intestinal colic, diarrhea, borborygmus, abdominal pain with palpation;

- For hepatobiliary form: presence of skin pallor, right hypochondrium pain with palpation, diarrhea or constipation, borborygmus;
- For asthenoneurotic form: presence of skin pallor, fatigability, headache (for children under 3, the counterpart to headache were considered tearfulness and loss of emotional tonus), sleep disorder, and irritancy.

The laboratory investigations included: bacterioscopical analysis detecting *Giardia* cysts in stool samples, and EIA detecting *Giardia* antibodies.

Considering that detection of *Giardia* cysts with bacterioscopical analysis is low – according to the statistical data, up to 20% of cysts can only be detected – and depends on subjective factors, this method was not included into the study records.

The instrumental methods of examination included fixation of electric potential at the points: SPED 3-dex; IG-4 dex and sin; ND-3 dex and sin.; ND-4 dex and sin.

Table 1.

Dynamics of the core clinical symptoms, immunological indicators, and indicators of gastrointestinal organs' activity of patients suffering acute intestinal giardiasis, defined with the acupunctural diagnostic methods by Voll.

Symptoms		Groups of patients with acute intestinal giardiasis					
		1st group DETA-AP device N=12		2nd group DETA-AP device and medicated treatment N=12		3rd group Medicated treatment N=20	
		Quantity	%	Quantity	%	Quantity	%
Skin pallor	Before treatment	9	75	10	83	16	80
	After treatment	3	25	6	50	10	50
Flatulency	Before treatment	8	67	8	67	16	80
	After treatment	1	8	2	17	4	20
Intestinal colic	Before treatment	5	41	6	50	11	55
	After treatment	1	8	2	17	5	25
Diarrhea	Before treatment	4	33	4	33	8	40
	After treatment	1	8	0	0	5	10
Borborygmus	Before treatment	8	67	7	58	12	60
	After treatment	2	17	1	8	4	20
Abdominal pain with palpation	Before treatment	10	83	10	83	16	80
	After treatment	2	17	1	8	7	35

High titer of IgG antibodies detected by EIA	Before treatment	8	67	9	75	16	75
	After treatment	4	33	2	17	5	25
	After 3 months	1	1	1	8	4	20
Electro-acupunctural diagnostics by Voll (mean values)							
SPED 3-dex	Before treatment	12-25		13-27		13-28	
	After treatment	30-40		35-47		35-40	
IG -4 -dex	Before treatment	10-25		12-27		12-28	
	After treatment	30-45		40-50		25-45	
IG -4 -sin	Before treatment	25-30		20-30		25-40	
	After treatment	38-45		35-50		35-40	

Conclusions**:**

Among the observed clinical evidences of acute intestinal giardiasis are:

For the 1st group: the greatest dynamics when the initial signs of flatulency (8-fold decrease) and abdominal pain with palpation (5-fold decrease); considerably decreased borborygmus (by 4 times) and skin pallor (by 3 times); intestinal colic and diarrhea became twice as rare.

The indicators of specific antibody titers fell by one half.

Acupunctural indicators improved by 10-20 points.

For the 2nd group: abdominal pain with palpation decreased by 10 times; borborygmus – by 7 times; skin pallor – by 5 times; flatulency – by 4 times; intestinal colic – by 3 times.

The indicators of specific antibody titers fell by a factor of 5.

Acupunctural indicators improved by 15-25 points.

For the 3rd group: positive dynamics appeared in the decrease of flatulency and diarrhea (by 4 times); borborygmus (by 3 times), signs of other syndromes fell by one half.

The indicators of specific antibody titers fell by two third.

Acupunctural indicators improved by 5-7 points.

Table 2.

Dynamics of the core clinical symptoms, immunological indicators, and indicators of gastrointestinal organs' activity of patients suffering hepatobiliary form of chronic giardiasis, defined with the acupunctural diagnostic methods by Voll.

Symptoms		Groups of patients with hepatobiliary form of chronic giardiasis					
		1st group DETA-AP device N=8		2nd group DETA-AP device and DETA-RITM device N=8		3rd group Medicated treatment N=20	
		Quantity	%	Quantity	%	Quantity	%
Skin pallor	Before treatment	7	88	6	75	16	80
	After treatment	2	25	1	13	14	70
Right hypochon-drium pain with palpation	Before treatment	8	100	8	100	18	90
	After treatment	1	1	1	1	6	30
Bitter taste in the mouth	Before treatment	5	63	4	50	11	55
	After treatment	1	13	0	0	8	40
Diarrhea or constipations	Before treatment	4	50	3	38	8	40
	After treatment	2	25	1	13	11	55
Borborygmus	Before treatment	8	67	7	58	12	60

	After treatment	2	25	1	13	4	20
High titer of IgG antibodies detected by EIA	Before treatment	7	88	6	75	16	75
	After treatment	5	63	3	38	12	60
	After 3 months	2	25	1	13	8	40
Electro-acupunctural diagnostics by Voll (mean values)							
SPED 3-dex	Before treatment	10-25		10-27		10-28	
	After treatment	30-40		35-45		30-45	
IG -4 -dex	Before treatment	10-25		12-27		12-28	
	After treatment	30-45		40-50		25-40	
IG -4 -sin	Before treatment	10-30		20-30		25-30	
	After treatment	38-45		35-50		35-30	

Conclusions**:**

In the 1st group: among the clinic evidences, the right hypochondrium pain almost completely disappeared; bitter taste in the mouth decreased by 5 times; there was 3-fold decrease of skin pallor; borborygmus, diarrhea (constipations) occurred half as often.

Over time, specific antibodies titers fell by two third. Acupunctural indicators increased by 10-15 points.

In the 2nd group: right hypochondrium pain completely disappeared; there was a 6-fold decrease of skin pallor, 4-fold decrease of borborygmus, and 3-fold decrease of diarrhea (constipations). The specific antibody titers fell by a factor of 5. Acupunctural indicators improved by 25-30 points

In the 3rd group: borborygmus and right hypochondrium pain occurred three times as rare; bitter taste and diarrhea (constipations) decreased by 1.5-2 times; at the same time, skin pallor of almost all group patients remained. Acupunctural indicators decreased (worsen) by an average of 5 points.

Table 3.

Dynamics of the core clinical symptoms, immunological indicators, and activity indicators of gastrointestinal organs and nervous system of patients suffering asthenoneurotic form of chronic giardiasis, defined with the acupunctural diagnostic methods by Voll.

Symptoms		Groups of patients with hepatobiliary form of chronic giardiasis					
		1st group DETA-AP device N=10		2nd group DETA-AP device and DETA-RITM device N=8		3rd group Medicated treatment N=20	
		Quantity	%	Quantity	%	Quantity	%
Skin pallor	Before treatment	2	70	6	75	18	80
	After treatment	2	25	1	13	12	60
Fatigability	Before treatment	9	90	8	100	18	90
	After treatment	2	20	1	13	10	50
Headache	Before treatment	5	50	4	50	12	60
	After treatment	1	10	0	0	8	40
Sleep disorders	Before treatment	4	40	3	38	10	50
	After treatment	2	20	1	13	10	50
Irritancy	Before treatment	3	30	4	50	10	50
	After treatment	2	25	1	13	8	20
High titer of IgG antibodies detected by EIA	Before treatment	8	80	6	75	16	80
	After treatment	3	30	2	25	12	60
	After 3 months	2	20	0	0	6	30
Electro-acupunctural diagnostics by Voll (mean values)							
SPED 3-dex	Before treatment	12-25		13-27		13-28	
	After treatment	30-40		35-47		30-40	
IG -4 -dex	Before treatment	10-25		12-27		12-28	

	After treatment	30-45	40-50	25-45
IG -4 -sin	Before treatment	25-30	20-30	25-40
	After treatment	38-45	35-50	35-40
ND -3 -dex	Before treatment	20-30	20-30	20-30
	After treatment	25-40	35-45	25-30
ND -3 -sin	Before treatment	20-30	20-30	20-30
	After treatment	25-40	35-45	25-30
ND -4 -dex	Before treatment	15-25	15-25	20-25
	After treatment	20-35	35-45	20-25
ND -4 -sin	Before treatment	15-25	15-25	15-25
	After treatment	20-35	35-45	15-20

Conclusions:

In the 1st group: the patients suffered headache less often (5-fold decrease); fatigability decreased by 4 times; skin pallor decreased by 3 times; the sleep disorders decreased by half; however, the irritancy remained for the majority of the patients.

There was a 4-fold decrease of the specific antibody titers over time. Acupunctural indicators increased by 15-20 points.

In the 2nd group: after the treatment, nobody complained on headache; the fatigability has noticeably disappeared (8-fold decrease); and skill pallor evidences has reduced by 6 times; irritancy decreased by 4 times; sleep disorders decreased by 3 times.

The specific antibody titers fell by a factor of 5 and were completely “gone” after 2-3 months. Acupunctural indicators improved by 25-30 points

In the 3rd group: all the indicators decreased by 1.5-2 times, while almost all patients still had sleep disorders.

The specific antibody titers fell by two third but they remained in the samples of 1/3 of the examined patients after 3 months. Acupunctural indicators improved by 5-10 points comparing to

the initial data.

Acceptability. It should be noted that the therapy with the DETA device is well tolerated by patients; there are also no general or local side effects of treating acute and chronic giardiasis. As for the subjective sensations: 5 patients with acute giardiasis (40%) had short-term “hot” feeling in the upper abdomen; and during the first 1-3 sessions with the DETA-AP device, third of the patients pointed the starting or growing pain in the upper abdomen for 10-15 minutes after the procedure.

The instrumental therapy of the DETA-AP and DETA-RITM devices had no negative impact on the development of comorbidity of the examined patients.

Conclusions.

1. By its functional and operational qualities, the DETA device (with the software ‘AP’) completely meets the requirements of medical practices in the field of the treatment of acute intestinal giardiasis.
2. By its functional and operational qualities, the DETA device (with the software ‘AP’) completely meets the requirements of medical practices in the field of the treatment of hepatobiliary form of chronic giardiasis.
3. By its functional and operational qualities, the DETA device (with the software ‘AP’) completely meets the requirements of medical practices in the field of the treatment of asthenoneurotic form of chronic giardiasis.
4. By their functional and operational qualities, combined use of the DETA device (with the software ‘AP’) and the DETA-RITM device (with the software ‘RITM’) completely meets the requirements of medical practices in the field of the treatment of hepatobiliary form of chronic giardiasis.
5. By their functional and operational qualities, combined usage of the DETA device (with the software ‘AP’) and the DETA-RITM device (with the software ‘RITM’) completely meets the requirements of medical practices in the field of the treatment of asthenoneurotic form of chronic giardiasis.
6. Comparing to the traditional methods of treatment, the higher clinical effect was

demonstrated when applying the DETA device – as monotherapy and together with medicated therapy.

7. (DUBLICATED!) Comparing to the traditional methods of treatment, the higher clinical effect was demonstrated when applying the DETA device – as monotherapy and together with medicated therapy.
7. Compared to the use of the DETA-AP device as monotherapy, the higher clinical effect was noticed when combined use of the DETA-AP and DETA-RITM devices for the treatment of hepatobiliary form of chronic giardiasis.

7. Compared to the use of the DETA-AP as monotherapy, the higher clinical effect was noticed when combined use of the DETA-AP and DETA-RITM devices for the treatment of asthenoneurotic form of chronic giardiasis.

8. No contradictions for using the DETA devices (DETA-AP or combined DETA-AP and DETA-RITM) for the treatment of patients with acute and chronic giardiasis were found out.
9. The combined use of the DETA devices is possible in a hospital, on an outpatient basis, and domiciliary.

Recommendations

For the foregoing reasons, based on the clinical study we propose to complement the regional standard of equipment in outpatient and inpatient facilities – minimal requirements are determined with the Order No.753 of Ministry of Health and Social Development, December 1, 2005 – with the following items:

1. Office of a family doctor (Annex to the Order No.No.1- of Ministry of Health and Social Development):
   The therapeutic device DETA with the installed ‘AP’ and ‘RITM’ software;
2. Office of a gastroenterologist (Annex to the Order No.No.1- of Ministry of Health and Social Development):
   The therapeutic device DETA with the installed ‘AP’ and ‘RITM’ software;
3. Office of a pediatric physician (Annex to the Order No.No.1- of Ministry of Health and

Social Development):

The therapeutic device DETA with the installed ‘AP’ and ‘RITM’ software.

In such a case, the therapeutic DETA devices (with the ‘AP’ and ‘RITM’ software) can be purchased either by using budget funds, or out of the patient funds for individual application.

The above-noticed recommendation will become legitimate with the Order by Regulatory Body of Regional Healthcare and will benefit the improvement of public health care.

Principal Investigators:

Candidate of Medicine ***Shkolnaya Olga NIkolaevna*** [Signature]

High level certificate Immunologist ***Iskhakova Antonina Fridrikhovna*** [Signature]

Research Adviser:

Candidate of Medicine, Professor ***Teregulova Zakiya Sagadatovna*** [Signature]

[Stamp]

Approved

by the Vice President on the scientific and research work, professor

[Signature] A.A. Panov

January 13, 2010

Report on the DETA device therapy effectiveness and the tolerance to the DETA device

The clinical approbation of the low-frequencies electromagnetic therapy DETA – RITM has been carried out at the State Educational Institution of the Higher Professional Education “Astrahan

State Medical Academy of the Federal Service on Surveillance in Healthcare and Social Development of the Russian Federation"

Table 1

Characteristics of the patients that were observed

Group	Number	
	Absolute	Proportionate
Main group	44	48%
Control group	47	52%

The purpose of the examinations was to study clinical effectiveness and tolerance of the DETA-RITM device in a complex therapy of stomach and duodenum.

Forty four persons aged from seventeen to fifty three years received the DETA-RITM therapy (the main group). The control group was composed of 47 persons of analogous age who didn't receive the therapy (Table 1).

The distribution of patients of the main group according to nosological forms is presented as follows (Table 2). Main group:

- Erosive gastroduodenitis – 11 persons,
- Stomach ulcer – 15 persons,
- Duodenal ulcer – 18 persons

Control group:

- Erosive gastroduodenitis – 12 persons,
- Stomach ulcer – 14 persons,
- Duodenal ulcer – 21 persons

Table 2

Distribution of the patients of the main and control groups according to nosological forms

Nosological form	Number of patients from the main group		Number of patients of the control group	
	Absolute	Proportionate	Absolute	Proportionate
Erosive gastroduodenitis	11	25%	12	26%
Stomach ulcer	15	34%	14	30%
Duodenal ulcer	18	41%	21	44%

At the moment of enrollment and registration at the clinic all the patients had the following clinical symptoms: pain in the area of epigastrium related to the food ingestion (hunger pains increasing after food), acid indigestion, abdomen heaviness (Table 3). Apart from that, the patients also had functional digestive system disorders, such as: constipations or diarrhea, meteorism, borborygmus, low appetite.

All the patients of the main and control groups were examined by doctor every day.

The DETA-RITM device therapy was prescribed to the patients of the main group in accordance with the instruction for use, 1 time per day. The course lasted for 3 weeks. Moreover, the patients of both groups received complex etiotropic and symptomatic therapy.

The period of adaptation passed well. Allergic reactions were not revealed.

Analysis of the clinical characteristics has shown that those patients who received DETA device therapy started to feel better and had the symptoms of digestive system functioning disorders reduced 2-5 days earlier than patients from the control group (tables 4, 5, 6).

Thus, adding DETA-RITM device therapy to the main treatment plan facilitates more early relief of the diseases' symptoms for 65 % of patients.

Table 3

Clinical symptoms

Nosological form	Symptoms					
	Pain in the area of epigastrium		Acid indigestion		Heaviness in in the area of epigastrium	
	Main group	Control group	Main group	Control group	Main group	Control group
Erosive gastroduodenitis	7 (64 %)	6 (50 %)	6 (55 %)	6 (50 %)	9 (82 %)	10 (83%)
Stomach ulcer	12 (80%)	13 (93%)	6 (40 %)	5 (36 %)	14 (93%)	11 (79%)
Duodenal ulcer	15 (83%)	17 (81 %)	16 (88%)	19 (91%)	10 (56%)	12 (57%)

Table 4

Dynamics of reduction of the clinical symptoms of erosive gastroduodenitis suffered by the patients of the main and control group (day of therapy)

Symptoms	Main group	Control group
Pain in the area of epigastrium	3rd day in 65 % of cases, 4th-5th day in 35 % of cases.	4th-5th day in 35 % of cases, 5th-7th day in 65 % of cases.
Acid indigestion	2nd-3rd day in 65 % of cases, 3rd-5th day in 35 % of cases.	3rd-5th day in 35 % of cases, 5th -7th day in 65 % of cases.
Heaviness in in the area of epigastrium	3rd day in 65 % of cases, 4th -5th day in 35 % of cases.	4th -5th day in 35 % of cases, 5th -7th day in 65 % of cases.

Table 5

Dynamics of reduction of the clinical symptoms of stomach ulcer suffered by the patients of the main and control group (day of therapy)

Symptoms	Main group (15 persons)	Control group (14 persons)
Pain in the area of epigastrium	3rd – 4th day in 65 % of cases, 4th – 5th day in 35 % of cases.	4th – 5th day in 35 % of cases, 6th – 7th day in 65 % of cases.
Acid indigestion	3rd day in 65 % of cases, 4th – 5th day in 35 % of cases.	4th day in 35 % of cases, 5th – 7th day in 65 % of cases.
Heaviness in in the area of epigastrium	3-4 day in 65 % of cases, 4-5 day in 35 % of cases.	4-5 day in 35 % of cases, 6-7 day in 65 % of cases.

Table 6

Dynamics of reduction of the clinical symptoms of duodenal ulcer suffered by the patients of the main and control group (day of therapy)

Symptoms	Main group (18 persons)	Control group (21 persons)
Pain in the area of epigastrium	3rd - 4th day in 65 % of cases, 4th - 5th day in 35 % of cases.	6th – 7th day in 35 % of cases. 7th – 8th day in 65 % of cases.
Acid indigestion	4th day in 65 % of cases, 5th day in 35 % of cases.	6th – 7th day in 35 % of cases, 8th day in 65 % of cases.
Heaviness in in the area of epigastrium	3rd- 4th day in 65 % of cases, 4th – 5th day in 35 % of cases.	6th - 7th day in 35 % of cases, 7th - 8th day in 65 % of cases.

DETA-RITM therapy was well tolerated by the patients. It also went well together with other pharmaceutical means of symptomatic and etiotropic therapy.

Moreover, positive corrective influence of the DETA-RITM device on the microbiocenosis of intestinal tract led to the normalization of the bowel movement, decreasing of dyspeptic effects (meteorism, borborygmus , appetite disorder) suffered by the patients with stomach ulcer and duodenal ulcer as a result of the etiotropic antimicrobial therapy.

Responsible for the research

Assistant of the department of propaedeutics of internal diseases

State Educational Institution of the Higher Professional Education

"Amursk State Medical Academy of the Federal Service on Surveillance in Healthcare and Social Development of the Russian Federation"" [Signature]

November 11, 2009

Approved:

by the Head of the hospital

of the Federal State Institution Penitentiary Institution IZ-77/1

of the Federal Service for the Execution of Sentences Administration in the city of Moscow

[Signature] Mazurov S.N.

[Stamp] September 26, 2007

Reference

on the tuberculosis screening diagnostics by the VRT (vegetal resonance testing) method performed among the special squads of the Federal State Institution

Penitentiary Institution IZ-77/1 of the Federal Service for the Execution of Sentences Administration in the city of Moscow.

The goals of the research

Defining the suitability of the VRT method for the mass diagnostics of the tuberculosis screening.

Materials (means) and methods

The examinations were performed using the DETA-Professional device developed and produced by the LLC Scientific Development and Production Enterprise “ELIS” in the city of Moscow.

The device is approved for the exploitation and is produced on the basis of the registration certificates and licenses of the Federal Service on Surveillance in Healthcare and Social Development of the Russian Federation.

The research was conducted using the methodological recommendations No. 99/96 on “Electropuncural vegetal resonance testing” approved by the Ministry of Healthcare of the Russian Federation as of April 7, 2000.

Results of the examinations and research.

In August – September 2007 the examination of the special squads of the Penitentiary Institution IZ-77/1 based on the tuberculosis diagnostics by the VRT method was carried out. Totally, 100 persons aged from 18 to 59 years have been examined. The examinations results achieved by using the VRT method were compared with the data of the film fluorography.

a) absolutely negative results - 91% (coincidence of negative results by the VRT method and photoroentgenography).

b) absolutely positive results – 2% (coincidence of positive results by the VRT method and photoroentgenography).

Given options correspond to the “correct” diagnostics of existence or absence of the disease and constitute 93%.

False positive results constitute 7 % (VRT diagnostics).

Additional examinations are needed to define if the patients have MBT (tuberculosis mycobacteria).

Conclusions

1. The VRT method allows to carry out screening diagnostics of the tuberculosis.

2. The method combines high sensibility, specificity and high diagnostic speed (10-15 minutes)

3. Expenses on performing examinations are minimal.

4. Combining the given method with traditional microbiological methods considerably increases diagnostic capacities of practical phtisiology.

5. The method may be recommended as the basic method for mass tuberculosis examinations of the population.

The examinations and research were carried out by the doctor phthisiatrician Sheshukov P.F. [Signature]

Report of the tuberculosis department [Stamp]

of Stavropol State Medical Academy

on the approbation of the DETA-AP device

(for the period of 6 months from June 2010 till December 2010)

The regional antituberculous health center (for 525 beds) provides therapy to the patients with pulmonary tuberculosis (children, teenagers, adults), spinal tuberculosis, knee-joint tuberculosis, eyes tuberculosis.

Totally 1159 patients with the above mentioned localizations of the tuberculosis have been treated in the year 2010. 89 % of the patients with the pulmonary tuberculosis had an open form of tuberculosis, 82.5% of the patients had disintegrated cavities. 48.9 % of the patients had a medication resistant form of the tuberculosis; 78.5% of the patients had a toxic syndrome; 56.5% of the patients had poor tolerance to the medication caused by toxic and toxic allergic reactions.

86.9% of the patients had tuberculosis accompanied by other diseases: 38.5% - diabetes mellitus, 29.6% - stomach diseases, 48.6% - liver diseases, 72.5 % - COPD (Chronic Obstructive Pulmonary Disease), more often chronic bronchitis, etc.

The following regimes were set:

1. Human tuberculosis:

-Tuberculosis – 3240;

-Tuberculosis basic – 5640;

-Tuberculinum nosod. – 1200;

2. For elimination of methysis:

- Lymth and detoxication – 3960;

3. Medication resistant forms of tuberculosis:

- Tuberculosis Klebsiella –1200;

- Tuberculosis rod – 840;

- Tuberculosis rod E coli infections – 600;

4. Recovery (after the end of the therapy)

5. Bacterial infection – 1560;

6. Lymphadenitis – 1200;

X-ray control was made after 3-6 months.

25 patients have been treated with the use of the DETA-AP device therapy: 13 persons with lungs affection-infiltrative tuberculosis with localization in cavities in the disintegration phase BK+ (Bacterium Koch+);

4 persons –tuberculous papillitis BK+;

5 persons- eyes tuberculosis;

3 persons– teenagers – tuberculous plevritis;

Drug-induced treatment was provided to the patients in accordance with I and II-B regimes. The improvement of the patients' health condition was noticed after 15-20 days. Based on the results of the treatment a good therapeutic effect could be noticed earlier than in the control group where patients didn't receive the DETA-AP device therapy.

It could be noted that all regimes and programs of the DETA-AP were well tolerated both by children and adults. As well, no side effects were noticed during the DETA-AP device therapy.

Conclusion

Based on the preliminary results, it can be stated that using electromagnetic therapy devices DETA-AP increases the effectiveness of the infection diseases treatment, in particular, tuberculosis. The DETA-AP therapy may be used at in-patient facilities, outpatient facilities and at home.

Attachment. Table

The result of the lungs tuberculosis therapy

	Number of patients			After 3 months of therapy		After 6 months of therapy	
	Absolute number	Out of them					
		MBT(+)	KV(+)	MBT(-)	KV(-)	MBT(-)	KV(-)
Main group CT (chemical therapy) + DETA-AP	13	13	13	7	7	13	13
		100%	100%	53.8%	53.8%	100%	100%
Control group CT (chemical therapy)	39	39	39	18	13	27	35
		100%	100%	46.1%	33.3%	71.5%	89.9%

December 12, 2010 Head of the department, professor [Signature]

Protocol

of the clinical research

[Stamp]

Chief doctor of the municipal unitary enterprise "Manual Therapy Center"

Novikov Yu.O.

March 30, 2010

on the DETA device therapy effectiveness

The goals of the research

1. To define the effectiveness of the DETA device therapy for the treatment of the thyroid gland pathology:

а) as a monotherapy;

б) as a part of the complex therapy, the place of performance: municipal unitary enterprise “Manual Therapy Center” in the city of Ufa, doctor endocrinologist with the highest doctor category Pervushina Vera Yurievna.

The results of the research:

Research on the clinical effectiveness of the DETA-RITM therapy was conducted among 67 women aged from 24 to 79 years (average age +/- 54.6).

The diagnosis was set by the clinical method and confirmed by ultrasound investigation and hormones analysis. The research covered the patients who had a big volume of the thyroid gland (from 36.8 to 82.6 $cm^{3)}$, the age more than 70 years, thyroid swellings (nodosities) more than 2-3 cm., heavy cardiovascular pathology, and health condition not allowing surgical interference.

After the conduction of the DETA therapy program “Thyroid gland” for 10 minutes during 6 days the thyroid gland of the 8 patients (who had the diagnosis of diffuse-nodular goiter) was modified. It increased in total volume for 2.1 mm. in some cases, and for 5.3 mm. in other cases. At that, however, the redistribution in volume of cavities and decrease of the size of the nodosities was registered. Moreover, the internal structure of thyroid swellings (nodosities) softened, cysts with the size of 17.0 ×6 mm. disappeared, formations without capsules diminished from the size 10×6 mm. and 9×6 mm. to 2mm. and 5 mm.

Longer observation of the patients with nodular goiter showed that after the conduction of 6 courses of the DETA device therapy the slow dynamics was noted. Small thyroid swellings (nodosities) and cysts disappeared, the structure improved, echogenicity changed but the size of the old nodosities didn’t change considerably. However, some stabilization could be determined – the growth of the formations stopped.

For obtaining better effect the program was complicated – it included frequencies to influence the pituitary and to normalize metabolism, sessions were prolonged up to 40 minutes. The therapy was conducted regularly.

Finally we have succeeded not only in diminishing the total volume of the thyroid gland but also the size of the thyroid swellings (nodosities). The total volume of the thyroid gland decreased from 40.4 $см^3$ to 36.4 $см^3$, thyroid swelling (nodosity) decreased from 47.4×30.1×43.6 мм. to 31.0×38.9×46.1 мм.

After the third session of the program "Thyroid gland hyperfunction" performed for 40 minutes for the patients with the Graves' disease the euthyroidism was achieved - the sphygmus decreased from 102 to 76 beats per minute, and the size of the thyroid gland diminished almost twice.

This program had also a good result in treating the patients with autoimmune thyroiditis (Derbyshire neck of the IV level), hyperfunction.

After 4 sessions the sphygmus decreased from 123 to 72 beats per minute, and the size of the thyroid gland diminished from 96 $см^3$ до 67.5 $см^3$. The results of the analysis of the thyroid gland hormones also showed the changes. Before the therapy the numbers were as follows: TSH (thyroid stimulating hormone) 0.01; T4 free – 30.0; autoantibodies to MSF (+) (microsomal fraction). After the therapy, the analysis showed the following results: TSH – 0.2; T4 free– 11.0, autoantibodies to MSF (+). The DETA device therapy was carried out in combination with thyrostatic medication (mercazolilum, 5mg., overall day dose of 30 mg., with its gradual reduction and addition of Euthyrox 50, with 25 mg. dose). This has proved once more the effectiveness of the combination therapy.

Small cysts in the thyroid gland disappear after one therapy course, the structure of big cysts changes, their parietes thicken, their content becomes more homogenous and dense.

Conclusion

- The program “Thyroid gland hyperfunction” run for 40 minutes had good results – the euthyroidism was achieved fast, the thyroid gland decreases considerably in size and becomes softer and more elastic.

- The combination therapy shows more effective results.

- Short 10-minutes long programs are suitable for preventive care courses with the aim of thyroid gland structure improvement for the patients living in the regions with the iodine deficit.

- Suitable for the therapy of nursing (lactating) women who have counter indications for thyroid hormones medication.

-It is suggested to have everyday sessions which may be possible upon purchase of the device for the private use.

Endocrinologist [Signature] Pervushina V.Yu.

Protocol

of the clinical research

[Stamp] “Approved”

Chief doctor of the Municipal Enterprise out-patient clinic No. 52 of the Kirovsky district of the city region of the city of Ufa

[Signature] Ismagilova R.M.

April 5, 2010

on the DETA device therapy effectiveness

City of Ufa, Republic of Bashkortostan

The basis for the conduction of the research:

The agreement on the conduction of the post-registration clinical approbation as of March 28, 2009.

Duration of the research: May 4, 2009 – March 31, 2010.

The purpose of the research: to estimate the capacities of the DETA device produced by the LLC Scientific Development and Production Enterprise “ELIS” in the medical practice on the territory of the Russian Federation.

Type of research: open nonrandomized comparative.

The tasks of the research:

1. To define the clinical effectiveness of the DETA device therapy as a monotherapy.
2. To study the clinical effectiveness of the DETA device therapy as a part of a complex therapy.
3. To estimate the safety of the conduction of the DETA device therapy.

The place of the research conduction: Municipal Enterprise outpatient clinic No.52 of the city of Ufa.

For conducting the research we have been provided with:

1. The DETA device produced by the LLC Scientific Development and Production Enterprise “ELIS” (Moscow) - 2 items; the DETA device Software provided for the antiparasite and therapeutic use.
2. The DETA device approved for the exploitation in the medical practice.
3. Operation manual for the DETA device.
4. Methodological recommendations. Diagnostics and therapy methodology is protected by the patent No. 2000114578 as of March 3, 2003, legally used by the LLC Scientific Development and Production Enterprise “ELIS”.

Examinations and treatment were carried out on the basis of the voluntary informed consent of the patients in accordance with the Order No.163 (OST 91500.14.0001- 2002) of the Ministry

of the Healthcare of the Russian Federation. The prior consent of the Ethical Committee was received for conducting the research.

The results of the research:

The study of the clinical effectiveness was carried out among 293 patients (76 men and 217 women), aged 18-70 (the average age - 52 years). The diagnosis was set by the clinical method and was confirmed by the microbiologic analysis data.

Methodology of the research:

Before the treatment session the DETA device was prepared for work in accordance with the instructions of the Operation manual for the DETA device. It was switched on and off in accordance with the instructions of the above mentioned manual.

During the session the device was located directly on the body of the patient in the "view" of the sick organ. The duration of the sessions varied from 1.5 to 2.5 hours. The session was run once a day. The course lasted from 10 to 30 days depending on the pathology.

The evaluation of the therapeutic effectiveness was carried out through everyday clinical examinations that included assessment of the overall health condition, estimation of pain according to visual analogous scale, assessment of the eye-ground condition and visual fields, measurement of intraocular pressure (IOP) and arterial blood pressure (ABP). We have also made analysis of the peripheral blood index, urine tests, biochemical analysis, vegetative resonance testing, as well as assessed the subjective perceptions of the patients' health condition before and after the therapy.

Tolerance

It should be noted that the patients had good tolerance to the DETA device. The DETA therapy didn't cause overall or local side effects during the treatment of the majority of patients. The therapy didn't have any negative influence on the duration of the associated pathology of the patients being examined. If the patients had a serious pathology or purulent (pyogenic) infection they received the complex therapy.

Clinical effectiveness of the treatment with the medical devices of the electromagnetic therapy DETA

Nosology	**Main group treated with the DETA therapy**			**Control group treated with the medication therapy**		
	N	**Average duration of therapy**	**Clinical effectiveness %**	**N**	**Average duration of therapy**	**Clinical effectiveness %**
Joints diseases 1. Reactive arthritis	**53** 22	21	70	24	21	50
2. Rheumatoid joint inflammation	8	21	66	25	21	40
3. Arthropathy deformans (degenerative osteoarthrosis)	23	14	60	25	14	53
Systemic vascular resistance diseases 1. Hypertensive disease	**22** 8	14	75	12	14	50
2. Atherosclerosis of blood vessels of lower extremities	6	14	67	8	21	54
3. Phlebeurysm	8	14	63	10	21	56
Gastrointestinal tract diseases 1.Pancreatitis	**22** 10	10	80	10	21	74
2. Cholecystitis	5	14	80	6	14	78
3. Duodenal ulcer	7	21	75	10	21	63
Eyes diseases 1. Myopia	**27** 7	21	43	12	21	33

2.Glaucoma	10	21	66	10	21	45
3. Retinal degeneration	5	21	60	5	21	20
4. Iridocycitis	5	14	60	5	21	40
Nervous system diseases 1. DEP (dyscirculatory encephalopathy)	**16** 7	21	80	10	21	60
2. Osteochondrosis	9	14	89	10	14	70
Surgical diseases 1.Purulent (pyogenic) infections	**51** 40	8	90	45	14	78
2.Trophic ulcer	**7**	21	57	10	21	50
3.Angiopathy accompanying pancreatic diabetes	4	21	50	6	21	33
Contagious diseases Viral diseases 1.Herpes	**102** 7	15	100	8	15	38
2. Coxsackie virus	1	21	100	2	21	0
3.Virus Epstein-Barr	12	21	100	14	21	0
Bacillary (bacterial) diseases 1.Mycoplasma	7	21	100	10	21	30
2.Streptococci	8	21	100	10	21	60
3.Staphylococci	6	14	100	8	14	62
4.Klebsiella pneumonic	2	21	100	4	14	30
5.Chlamydia	5	21	100	6	21	33
6.Helicobacter pylori	14	30	100	15	21	34
7.Candida	12	35	100	10	21	0
Parasitical 1.Lamblia	9	10	100	10	14	50
2**.**Ascarides	6	5	100	5	5	80
3.Seat worms	10	3	100	10	3	90
4. Opisthorchiasis	2	7	100	1	14	100
5. Toxoplasmosis	1	35	100	0	-	-

Conclusions:

- According to the results of the DETA devices therapy research, the clinical effectiveness is considerably higher in the main group than in the control group.

- It was noticed that according to the results of the vegetative resonance testing, it took 3 weeks for elimination of the Epstein-Barr virus, herpes, mycoplasma, chlamydia, chronical streptococcus infection. It took no fewer than 30-35 sessions for the treatment of the toxoplasmosis, candidosis, helicobacter pylori. It is necessary to run the DETA-AP program several times per day (up to 5 times per day) if the contagious diseases are in the critical phase or purulent processes are noticed.

- When using in surgery for the treatment of purulent processes the resolution of purulent processes happened in most cases on the 3^{rd} – 4^{th} day depending on the outspread and level of seriousness of the process. The complex therapy was applied. In the control group where the DETA-AP therapy was not conducted the resolution of the purulent process happened on the 6^{th} – 8^{th} day, granulations were formed on the10 – 12 day. Thus, the treatment duration shortened twice due to the DETA device therapy.

- The small percentage of improvement was noticed in the treatment of the trophic ulcer and angiopathy accompanied by other heavy pathology which requires long and complex treatment.

- For the treatment of the atherosclerosis we developed programs working on the frequencies focused on the improvement of microcirculation, oxygenation, decrease of cholesterine. The ready software complex Ulcer and Helicobacter pylori were used for the treatment of the duodenal ulcer. Addressing the eyes diseases we developed programs for the glaucoma treatment, as well as used the ready software complexes.

- It is necessary to conduct the therapy focused on the stimulation of functioning of the gastrointestinal tract, gall bladder, kidneys, lymphatic drainage, and blood circulation for the

treatment of any chronical pathology. Such programs as Active Protection, Deep Cleansing, Regulation of Blood Circulation and other standard programs had good results.

Conclusion:

1. According to the results of the research, medical devices of electromagnetic therapy DELTA showed high effectiveness in treatment of the contagious diseases. They showed good results in therapy of the chronical inflammation diseases and satisfactory level effectiveness in treatment of the degenerative diseases which require more long and complex therapy.
2. Counter indications for the use of the DETA devices series were not discovered.
3. The DETA device may be used at the in-patient facilities, outpatient facilities and at home.
4. The DETA-AP and DETA-RITM devices may be successfully used for the treatment of any disease which doesn't require urgent surgical interference, provided the correct diagnosis was set

Recommendations:

1. It's not advisable to attach the device to the head area, since headaches and arterial tension oscillations may occur.
2. At least 25-30 or more sessions are required for the treatment of the chronical pathology depending on the seriousness and outspread of the process.
3. To increase the effectiveness of the therapy it is necessary to use programs for the activation of the eliminative systems of the body – liver, kidneys, lymphatic drainage, as well as the programs for regulation of the immune, endocrine, cardiovascular and nervous systems.
4. For the guaranteed therapeutic effect the doctor's consultation is needed.

The research performed by:

Doctor – therapeutist, rheumatologist Vasiliyeva A.I.

Doctor – surgeon		Kolesnikova I.V.
Doctor – ophthalmologist	[Signature]	Gumerova E.I.
Chief doctor		Ismagilova R.M.

Protocol

of the clinical trial

[Stamp] "Approved"

Chief doctor of the Municipal Enterprise out-patient clinic No. 52 of the Kirovsky district of the city region of the city of Ufa

[Signature] Ismagilova R.M.

January 22, 2010

on the DETA device therapy effectiveness

City of Ufa, Republic of Bashkortostan

The basis for the conduction of the trial :

The agreement on the conduction of the post-registration clinical approbation as of March 28, 2009.

Duration of the research: October 1, 2009 – December 31, 2009.

The purpose of the trial: to estimate the capacities of the DETA device produced by the LLC Scientific Development and Production Enterprise "ELIS" in the medical practice on the territory of the Russian Federation.

Type of the trial: open nonrandomized comparative.

The objectives of the trial:

4. To define the clinical effectiveness of the DETA device therapy as a monotherapy.
5. To study the clinical effectiveness of the DETA device therapy as a part of a complex therapy.
6. To estimate the safety of the conduction of the DETA device therapy.

The place of the trial conduction: Municipal Enterprise outpatient clinic No.52 of the city of Ufa.

For conducting the trial we have been provided with:

5. The DETA device produced by the LLC Scientific Development and Production Enterprise “ELIS” (Moscow) - 2 items; the DETA device Software provided for the antiparasite and therapeutic use.
6. The DETA device approved for the exploitation in the medical practice.
7. Operation manual for the DETA device.
8. Methodological recommendations. Diagnostics and therapy methodology is protected by the patent No. 2000114578 as of March 3, 2003, legally used by the LLC Scientific Development and Production Enterprise “ELIS”.

Examinations and treatment were carried out on the basis of the voluntary informed consent of the patients in accordance with the Order No.163 (OST 91500.14.0001- 2002) of the Ministry of the Healthcare of the Russian Federation. The prior consent of the Ethical Committee was received for conducting the research.

The results of the trial:

The study of the clinical effectiveness was carried out among 73 patients (24 men and 51 women), aged 18-70 (the average age - 52 years). The diagnosis was set by the clinical method and confirmed by the microbiologic analysis data.

Methodology of the trial research:

Before the treatment session the DETA device was prepared for work in accordance with the instructions of the Operation manual for the DETA device. It was switched on and off in accordance with the instructions of the above mentioned manual.

During the session the device was located directly on the body of the patient in the "view" of the sick organ. The duration of the sessions varied from 1.5 to 2.5 hours. The session was run once a day. The course lasted from 15 to 30 days.

The evaluation of the therapeutic effectiveness was carried out through everyday clinical examinations that included assessment of the overall health condition, estimation of pain according to visual analogous scale, assessment of the eye-ground condition and visual fields, measurement of intraocular pressure (IOP) and arterial blood pressure (ABP). We have also made analysis of the peripheral blood index, urine tests, biochemical analysis, vegetative resonance testing, as well as assessed the subjective perceptions of the patients' health condition before and after the therapy.

The conducted treatment addressed the following pathologies:

I Surgery

- Atherosclerosis of the lower extremities blood vessels (Leriche's syndrome) – 6 persons.
- Varicose disease of the lower extremities blood vessels – 8 persons.
- Angiopathy accompanying the diabetes – 4 persons.
- Trophic ulcers – 7 persons.
- Raynaud's syndrome – 2 persons.
- Duodenal ulcer – 4 persons.

II Contagious diseases

- Toxoplasmosis – 1 person.
- Epstein-Barr virus – 9 persons.
- Mycoplasmosis - 7 persons.
- Coxsackie virus type B – 1 person.
- Candidosis of the intestinal tract – 12 persons.

- Helicobacter pylori – 8 persons.
- Reactive arthritis accompanied by the streptococcal infection – 4 persons.

Totally – 73 persons

Clinical effectiveness of treatment by the medical devices of the electromagnetic therapy DETA

Nosology	Number of patients	Improvement	%	Without dynamics/ progress	%
Leriche's syndrome	6	4	67	2	33
Varicose disease	8	5	63	3	38
Angiopathy	4	2	50	2	50
Trophic ulcers	7	3	43	4	57
Raynaud's syndrome	2	2	100	-	-
Duodenal ulcer	4	3	75	1	25
Toxoplasmosis	1	1	100	-	-
Epstein-Barr virus	9	9	100	-	-
Mycoplasma	7	7	100	-	-
Coxsackie virus	1	1	100	-	-
Candidosis	12	12	100	-	-
Helicobacter pylori	8	8	100	-	-
Streptococcus infection	4	4	100	-	-

It was noticed that according to the results of the vegetative resonance testing, it took 3 weeks for elimination of the Epstein-Barr virus, mycoplasma, chronical streptococcus infection. It took no fewer than 30-35 sessions for the treatment of the toxoplasmosis, candidosis, and helicobacter pylori. It is necessary to run the DETA-AP program several times per day (up to 5 times per day) if the contagious diseases are in the critical phase or purulent processes are noticed.

The small percentage of improvement was noticed in the treatment of the trophic ulcer and angiopathy accompanied by other heavy pathology which requires long and complex treatment.

For the treatment of the atherosclerosis we developed programs working on the frequencies focused on the improvement of microcirculation, oxygenation, decrease of cholesterine. The ready software complex Ulcer and Helicobacter pylori were used for the treatment of the duodenal ulcer.

Tolerance

It should be noted that the patients had good tolerance to the DETA device. The DETA therapy didn't cause overall or local side effects during the treatment of the majority of patients. The therapy didn't have any negative influence on the duration of the associated pathology of the patients being examined.

Conclusion:

1. According to the results of the research, medical devices of electromagnetic therapy DELTA showed high effectiveness in treatment of the contagious diseases. They showed good results in therapy of the chronical inflammation diseases and satisfactory level effectiveness in treatment of the degenerative diseases which require more long and complex therapy.
2. Counter indications for the use of the DETA devices series were not discovered.
3. The DETA device may be used at the in-patient facilities, outpatient facilities and at home.

Recommendations:

1. It's not advisable to attach the device to the head area, since headaches and arterial tension oscillations may occur.
2. At least 25-30 or more sessions are required for the treatment of the chronical pathology depending on the seriousness and outspread of the process.

The research performed by:

Doctor – therapeutist, rheumatologist		Vasiliyeva A.I.
Doctor – surgeon		Bikmetova I.F.
Chief doctor	[Signature]	Ismagilova R.M.

Protocol

of the clinical trial

[Stamp] "Approved"

by the Head of the department of physiotherapy

of the Faculty of the Doctors' Expertise Advancement

of the N.N. Burdenko Voronezh State Medicl Academy

[Signature] professor V.A. Borisov

March 26, 2005

of the DETA devices of the electromagnetic therapy

(city of Voronezh)

From April 12, 1997 until the present time the work on using three models of medical devices of electromagnetic therapy DETA (DETA-UDT, DETA-7, DETA-8) in treatment of diseases of the genitourinary organs of men is being conducted in the andrologist's office. The devices are designed for influencing a man's organism by a weak electromagnetic field with carrier frequency 10 kHz and therapeutic impulses in a frequency range from 0.1 to 100 Hz. The microprocessor is used in the devices. Depending on the set program, the microprocessor forms

signals in a form of a set of frequencies. Time of work of the device at each frequency and a set of frequencies for each pathology was assigned in accordance with methodological recommendations given by the LLC Scientific Development and Production Enterprise “ELIS”. We developed particular methods for treatment of a range of urological diseases. Before receiving the treatment the patients were examined. The patent No. 2000114578 issued on March 20 2003 named “The method of the complex diagnostics of diseases of the organs of the urogenital system of men” was received for the examination method. Treatment of the patients was conducted at the in-patient facility, at home and in a combination of the first two ways.

Clinical effectiveness of the treatment by the DETA medical devices of electromagnetic therapy

Name of the disease	Total number of patients	Results of the treatment			
		Recovery		No changes	
		Number of patients	%	Number of patients	%
Chronic prostatitis	4800	4792	99.8	8	0.2
BPH (benign prostatic hypertrophy)	520	515	99.0	5	1.0
Chronic cystitis	38	38	100	0	0
Acute urethritis	92	92	100	0	0
Chronic pyelonephritis	456	456	100	0	0
Kidney stones	52	50	96.1	2	3.9
Kidney cyst	12	12	100	0	0
Oligozoospermia	15	15	100	0	0
Renal collic	3	3	100	0	0

Oxalate-, phosphate-, uraturia	235	235	100	0	0
Erectile dysfunction	37	37	100	0	0

All patients tolerate procedures well, side effects and deviations were not observed. Only one patient did not tolerate the treatment with «DETA» device. But he also did not tolerate any other physical therapy treatment. Number of the conducted procedures varied from 1 to 60. A huge set of frequencies allows a doctor to create individual treatment programs depending on combination of diseases and to conduct them at the same time. If patients have their own portable devices it allows them to conduct the treatment at home and at work.

Conclusion: medical DETA devices of electromagnet therapy are recommended to be used for treatment of tens of millions of sick men. This will allow them to cure annoying diseases in short terms without surgical intervention, spending insignificant amount of money for it.

Doctor – urologist [Stamp] [Signature] Chornyh Viktor

[Stamping]

Non-Governmental Healthcare Institution

The Road Policlinic at the station Voronezh-1

JSC "Russian Railroad"

Revolyutsii prospekt, 2, city of Voronezh, 394000

Tel/fax: 65-33-53

1. For the conduction of the clinical trial the Road clinic of the Voronezh city was supplied with two models of the medical device of electromagnetic therapy - DETA and DETA-7 (with seven treatment programs). Devices form the impulses of electromagnetic field in accordance with the program set by a doctor. The frequencies of the device's function range from 0.1 Hz to 100

Hz. The adjusting frequency step is 0.01 Hz. DETA medical device is quite convenient and simple in exploitation. It doesn't have significant weight and dimensions. A charging source (of) DETA-7 is a battery with voltage of 9V which provides operation of the device during 15 hours (approximately 20-25 treatment sessions).

2. Medical tests of the effectiveness of treatment with the device were conducted among 161 patients with different pathologies and levels of severity of the pain syndrome.

DETA medical device of electromagnet therapy was used:

- to stop the acute attack of bronchospasm – 25 patients;
- for treatment of acute urethritis – 18 patients;
- for treatment of exacerbation of chronic prostatitis – 30 patients;
- for treatment of kidney stones disease – 4 patients;
- for treatment of benign prostatic hyperplasia (adenoma) of the prostate – 7 patients;
- for treatment of varicose disease of the lower extremities (the acute stage) – 14 patients;
- for treatment of allergic dermatitis – 12 patients;
- for treatment of fibroadenoma of the uterus – 5 patients.

CONCLUSIONS.

Research of the treatment effect during the use of the devices (including the results of laboratory analysis, ultrasound diagnostics) shows, that application of the device cause specific and nonspecific reactions in an organism.

NONSPECIFIC EFFECTS OF THE THERAPEUTIC IMPACT INCLUDE:

- improving of microcirculation;
- spasmolytic effect (smooth muscle relaxation); anesthesia;
- improving of the indexes of arterial and venous pressure; improving of the central nervous system, endocrine and cardiovascular systems functioning;
- increasing of the immunological reactivity and resistance to infectious agents;
- improving of the carbohydrate metabolism, decreasing of a level of the uric acid.

Including the DETA devices therapy as a part to a complex of the treatment arrangements facilitates:

- more early cure and, in most cases, disappearance of clinical signs of diseases;

- normalization of the results of clinical and laboratory tests; improving or normalization of immunological indexes.

Use of the device for the therapy allows:

- to significantly diminish the volume of the medication therapy;
- to refuse almost totally from using analgesic, spasmolytic, general regulating medication means;
- to decrease the number of courses of medicament treatment; to fully refuse from using of medication among a range of patients and to make using of the device the main treatment method; to decrease allergy effects of the patients, to increase immunity power of the body;
- to speed up the healing process or remission, and, thus, to decrease the duration of the treatment.

Conclusion.

Portability and simplicity of exploitation of the DETA medical device of electromagnetic therapy allows to use it in clinics, sanatoriums and outpatient facilities.

An important characteristic of the device is a possibility of its use at home and in field conditions. Any failures in the device's work were not observed.

[Signature] [Stamp]

The results of the clinical trial of the medical devices

[Stamping]

The Regional children's hospital No.1

Health resort for children

Voronezh region

of the electromagnetic therapy DETA May 13, 2005

Since March 2003 until April 2005 at the physiotherapy department of Chertovitskiy health resort for children of the Regional children's hospital No.1 the work on testing of the following medical devices of electromagnetic field therapy: DETA-8, DETA-7, DETA-UDT was conducted.

The devices are designated to influence the human's organism with a weak electromagnetic field with the carrier frequency 10 KHz and therapeutic impulses in a range of frequencies from 0.1 to 100 Hz. Time of the device's work at each frequency and a set of frequencies for each pathology was set in accordance with the methodical recommendations.

Estimation of the effectiveness of the conducted treatment was based on conventional clinical diagnostic indexes and subjective feelings of patients, their observation by specialists before and after the conducted treatment courses, and making appropriate analysis and probes (tests).

The treatment was provided to 341 patient at the age from 7 to 15 years:

- with the pathology of eyesight (myopia, hyperopia, astigmatism) – 166 patients;
- with the pathology of the gastrointestinal tract (chronical gastroduodenitis, chronic colitis, dyskinesia of biliferous tract) - 18 patients;
- with disorders of the autonomic nervous system (syndromes of autonomic dysregulation: hypotension, sympathetic tone, mixed) - 130 patients;
- with the pathology of musculoskeletal system (osteochondrosis, scoliosis) – 18 patients;
- with the pathology of the respiratory system (bronchial asthma, bronchitis) - 9 patients.

Deterioration of the condition during the treatment course and afterwards was not noticed. A positive dynamics was noticed already after the second-fourth procedure. Estimation of the effectiveness of the conducted treatment was based on the common clinical and diagnostics approaches and on the subjective feelings of the patients. Improvement in the first group was achieved at 66%, in the second - 98.7%, in the third – 97.6%, in the fourth - 46%, in the fifth - 94,6 %. This treatment method is especially effective for treatment of the patients with vegetative deregulation, diseases of the gastrointestinal tract and of the patients with the pulmonological profile. As for the children with the gross organic pathology, we noticed improvement of the health condition, emotional tonus, increasing of an organism's strength, relieve of tension and irritability

in majority cases.

Conclusions:

1. Using of the DETA medical devices of electromagnetic field therapy is highly effective for treatment of different children's diseases, especially of the functional character.

2. Portability and simplicity of exploitation of the DETA medical devices of electromagnetic field therapy give a possibility to effectively use them in the pediatric practice, including children of the young age.

3. All patients tolerate the procedures well, side effects and complications were not observed.

Manager [Stamp] [Signature] Golubkova T.V.

The Regional children's hospital No.1

Chief doctor deputy in the resort affairs [Signature] Deineka A.D.

[Stamping]

Ministry of Healthcare of the Russian Federation

State Scientific Research Center of Preventive Medicine

City of Moscow

Protocol No. 7 as of December 5, 1997

on the medical trial of the experimental model of the medical device for express-diagnostics, medical testing, and electro-acupunctural therapy the R. Voll method that was provided by the LLC Scientific Development and Production Enterprise "ELIS"

1. In the period from September 14, 1997 until December 1, 1997 the State Scientific Research Center of the Preventive Medicine conducted medical trial of the DETA device made by LLC Scientific Development and Production Enterprise “ELIS” for express-diagnostics, drug-induced testing and electro-acupunctural therapy by the method of R. Voll on the basis of the department of functional methods of observations.

The goal of the trial was to study technical and functional characteristics of the device, estimation of the possibilities of using the device in medical institutions of Russian Federation.

2. The study was supplied with:

а) DETA medical device,

- liners of hand electrodes (2 pieces),

- universal diagnostic sensitive element,

- cell for placement of ampoules,

- stand ditch,

- a set of wires - an additional active electrode with a set of tips.

б) a set of technical documentation for the device

- passport ЭИ04.001.996.009 ПС (draft)

- technical specifications ТУ 9441-001-27970873-94

3. Brief technical characteristics of the tested device and its designation.

Dimensions of the device 190x110x10 mm. Weight 0.5 kg. Power supply from the integrated into the device source of direct current or an external power source. There are indicators of the regimes, knobs and switches of the regimes of work on the device’s panel.

4. Medical tests

The DETA diagnostics device is designated for conduction of a diagnostics by the method of R. Voll, individual selection of medication, therapy with relaxation oscillations of low frequency,

and also for energy-informational transfer of medicinal properties of medicines (homeopathic, nosodes of organic toxines) to different carriers.

The method of electropunctural diagnostics is based on the interrelations of biologically active points lying on the surface of a body with internal organs and systems of the organism. Thus, the value of the electrical potential of these points is an indicator of the condition of the internal organs and systems of the human body.

The given DETA device of electropuncture diagnostics was tested on the basis of the Department of functional methods of observation of the Center of Preventive Medicine. The method was used at the stage of the primary screening observation.

We have analyzed acupunctural forms of 65 persons of both sexes with the age of 20-60 years. Each form included 90 measurement parameters. For the verification we used data of the instrumental methods applied at a standard clinic examination; spirofluometric and X-ray examination for estimation of the lungs condition; reovasography and Doppler sonography for estimation of the great vessels of the circulatory system; echocardiography (ECG) and vectorcardiography (VCG) of a heart; suprasonic and laboratory methods for estimation of liver, pancreas, kidneys, thyroid gland and genitourinary system condition; esophagogastrodudenoscopy and Ph-measurement for estimation of a stomach and a duodenum condition.

The researched method allowed to determine the “target organ” and the level of its affection by the following categories: norm, inflammation process, degenerative changes.

5. Results of the verification methods distributed to the analogous categories.

Information on diagnostics with the help of the DETA device	(%)
Among the patients with lungs diseases – sensitivity	91%
specificity	92%
among the patients with cardiovascular disease – sensitivity	87%
specificity	98%

among the patients with gall bladder diseases – sensitivity		85%
	specificity	81%
among the patients with the thyroid gland diseases –sensitivity		90%
	specificity	75%
among the patients with liver diseases – sensitivity		71%
	specificity	80%
among the patients with kidneys diseases – sensitivity		90%
	specificity	75%
among the patients with urogenital system diseases – sensitivity		73%
	specificity	91%

In the diagnostics of stomach diseases 100% sensitivity and specificity was noticed.

Doctor	[Signature]	V. S. Dmitrieva
Associate researcher	[Signature]	S.A. Martynchik
Head of the department	[Signature]	V.M. Shamarin

Experience of using the

[Stamp]

Veterinary station of the Ufa city

Vetrinary clinic “Nadezhda”

DETA-AP device (antiparasitic)

Goal of the research: to assess possibilities of using the DETA device made by LLC Scientific Development and Production Enterprise “ELIS” in veterinary practice at the territory of Russian Federation on the basis of the Ufa city veterinary station.

Objectives of the research:

1. To determine the clinical effectiveness of using the DETA device during treatment of diseases of small pets of inflectional and parasitic character as monotherapy and using the device in combination with the medicament treatment scheme.
2. To study the clinical effectiveness of using the DETA device as a part of the complex treatment of small pets diseases of inflectional and parasitic character.
3. To estimate safety of using the DETA device during treatment of small pets diseases of inflectional and parasitic character.

Research plan: conduction of clinical tests on small pets. Selection of sick animals was conducted in accordance with the selected criteria of inclusion.

Criteria of inclusion: cats, dogs, guinea pigs, hamsters were included into the research. Examination and treatment were conducted on the basis of the voluntary informed consent of the sick pets’ owners.

Place and time of conduction of the research:

Kuvykinskaya veterinary clinic of Ufa city veterinary station.

For conduction of the research we were provided with:

1. The DETA device made by LLC Scientific Development and Production Enterprise “ELIS” (Moscow) in the quantity of 1 piece; software program of the device providing antiparasitic therapy.
2. The DETA device approved for the use in medical practice (registration certificate of the Federal Service on Surveillance in Healthcare and Social Development of the Russian Federation No. __as of___)
3. Operational manual of the DETA device

4. Methodical recommendations

Method of diagnostic and treatment is protected by the patent No. 2000114578 as of March 20, 2003, legally used by LLC Scientific Development and Production Enterprise “ELIS”.

Treatment method. Before the treatment procedure was conducted the DETA device was prepared for operation in accordance with the guidance of the operational manual of the device. The device was switched on and switched off in accordance with the guidance of the manual. During conduction of a session, the device was in a close proximity from the patient’s body. The procedures lasted for 3-15 minutes; the number of procedures was 2 sessions a day; a course lasted from 3 to 21 days.

Assessment of the therapeutic effectiveness of different treatment methods was conducted on the basis of daily clinical observations, including assessment of the general condition of patients, dynamics of the body’s weight, condition of the functionality of the gastrointestinal tract, condition of animals’ skin and hair.

Among the laboratory tests we have performed analysis of excrements for parasitic worms’ eggs, analysis of urine, blood swabs for presence of causative agents of parasitic diseases, luminescent diagnosis, microscopial investigation of skin scrapings. Analysis of the patients’ health indexes before and after the treatment was made.

Clinical observations of the patients who received treatment with the device as a monotherapy and as a combined therapy, allowed to identify more vivid positive therapeutic effect in comparison with the control group (which received a standard medical treatment). The effect was expressed by a shorter term of the clinical signs of diseases disappearance.

Specific examples of using of the DETA-AP device.

1. Diagnosis - chronical purulent conjunctivitis. Apart from the symptomatic treatment, the DETA-AP device therapy was used with the following programs:

- Staphylococcus complex,
- Staphylococcal infection,
- Staphylococcus- streptococcus infection,
- Streptococcus pyogenic,
- Lymph and detox.

The treatment lasted for 10 days, the programs were used 2 times per day. The result of the

treatment was expressed in decreasing of the local inflammatory reaction of the soft tissues of the eye, changing of the character of secretions from eyes with the subsequent termination. The result of the treatment was evaluated as positive.

2. Symptoms of the constant soft stool which does not stop after antimicrobial therapy. Apart from the diet therapy and probiotics we also used the DETA-AP device with the following programs:

- Lymph and detox,
- Cryptosporidia,
- Leishmaniasis,
- Giardia intestinalis.

Duration of the treatment was 7 days, the session was run 1 time per day. Normalization of stool as noticed on the 4th-5th day of the treatment. Termination of the phenomena of the intestine dysbiosis. Complete recovery.

3. Abscesses of the cheek pouch of hamsters. After the surgical intervention the device was used with the following programs:

- Bacterial infections basic;
- Staphylococcus and streptococcus infection,
- Lymph and detox.

The treatment lasted 3-5 days, number of sessions -1 time per day. Complete recovery of the soft tissues. Appetite was recovered at the 3rd day of the treatment.

4. Diagnosis - acute cystitis. Along with the symptomatic therapy the DETA device was used with the following programs:

- General antiseptic,
- Lymph and detox.,
- Golden staphylococcus drug-resistant
- Staphylococcus and streptococcus infection. The treatment lasted for 7 days, number of sessions - 2 times per day. Due to the DETA devise therapy a faster disappearance of pain syndrome, improving of the general condition of the patient in comparison with the standard treatment scheme were noticed.

5. Diagnosis endometriosis.

Using of the device with the following programs:

- Endometritis,
- Ovaries,
- Staphylococcus and streptococcus infection,
- Lymph and detox,
- Catarrhal inflammation of uterine tubes.

Duration of the treatment - 10 days, number of sessions -1 per day. During the first 3 days of the treatment the increase of the volume of mucopurulent discharges from the uterus (cleansing if the cavity of the uterus) was noticed. After a week of the treatment positive changes in the pets' behavior (appearance of the appetite, increase of the motor activity, normalization of the body's temperature) were identified. Decrease of the size of uterus, cleansing of the uterus tubes cavity were observed during the ultrasonography examination. The result of the treatment was defined as positive. Disease recurrences were not observed.

6. Diagnosis kidney stones disease at cats. Along with the common treatment, the DETA device therapy was used by the following programs:

- Urinary bladder;
- Urinary bladder, weakness of the sphincter,
- Lymph and detox,
- Renal colics,
- Kidney stones disease,
- Bacterial infections basic.

Duration of the treatment - 14 days, 2-3 sessions per day.

After finishing the treatment the following positive changes in the condition of the pets were identified: normalization of the urination process, changing of the physical characteristics of urine (lack of blood, decreasing of the sediments of salts). This was proved by the laboratory analysis of the urine sediment. The result of the treatment may be considered as positive.

7. Conjunctivitis of guinea pigs was treated with using the antiseptic external means and with the DEAT device therapy run with the following programs:

- Animalculine,
- Staphylococcus and streptococcus infection;
- Lymph and detox,
- Bacterial infection basic.

Duration - 5 days, number of sessions – 1 per day. At the third day of the treatment termination of discharges from the eyes, disappearance of the nervousness of a pet, improving of the general condition of a patient were identified.

8. Diagnosis - enteritis.

Along with the symptomatic therapy the DETA device therapy was used with the following programs:

- Lymph and detox,
- Cryptosporidia,
- Leishmaniasis,
- Spastic colitis,
- Intestine bowel mucosa disorder,
- Intestine inflammation.

Duration of the treatment 4-5 days, number of sessions -2 per day. At the 3rd day of the treatment normalization of the digestion process, good appetite, lack of bulging syndromes and pain in the gastrointestinal tract were noticed. The result of the treatment was evaluated as positive.

9. Diagnosis - chronical endometritis of aged pets. Ovariohysterectomy was conducted. During the postoperative period the device was used with the following programs:

- Lymph and detox,
- Bacterial infection common,
- Staphylococcus and streptococcus infection.

We noticed faster recovery after the operation in comparison with the standard scheme of the treatment without using the DETA-AP device. Duration of the treatment - 8 days, number of sessions -1 per day.

10. Diagnosis - hematoma of the auricle, caused by the parasitic infection (Otodectosis). We used the DETA device with the following programs:

- Lymph and detox,
- Drainage,
- Mange,
- Follicular mite.

Duration of the treatment - 10 days, number of sessions -2 per day. We noted the high effectiveness of using the device without inclusion of the medication means in the treatment plan.

We stated the full relief of the pets from the ear mite confirmed by the microscopy of smears from the ears.

11. Diagnosis - generalized form of demodicosis. Along with the medication therapy the DETA device therapy was used with the following programs:

- Lymph and detox,
- Demodex (dog louse),
- Bed mites,
- Mange,
- Follicular mite,
- Staphylococcus and streptococcus infection.

Duration of the treatment - 21 days, number of sessions - 1 per day. Itching all over the body stopped, recovery of psycho-emotional state of the patient was noticed. Complete recovery of the pets was confirmed by the microscopy of skin scrapings.

12. Diagnosis - chronical inflammation of auricles with areas of the skin necrosis. The DETA device therapy was used as a monotherapy by the following programs:

- Staphylococcus and streptococcus infection,
- Lymph and detox,
- Mange,
- Follicular mite,
- Fungal infection,
- Funguses basic,
- Trichophyton basic.

Duration of the treatment 20 days, number of sessions - 2 per day. We noticed decrease of inflammatory and pain reactions on the 5th day of the treatment. The result of using the device was evaluated as positive.

13. Diagnosis - balanoposthitis. Along with the external disinfection means the DETA device therapy was used with the following programs:

- Staphylococcus and streptococcus infection,
- Lymph and detox,
- Elementary,
- Trichomonad,

- Ureaplasma.

Duration of the treatment - 10 days, number of sessions - 2 per day. We noticed termination of emission of ichorous smell on the 4th day of the treatment.

14. Diagnosis - chronical infection of eyes among young pets. Along with the external disinfection means the DETA device therapy was used with the following programs:

- Staphylococcus and streptococcus infection,
- Lymph and detox,
- Mycoplasma basic,
- Elementary,
- Clamidiosis,
- Respiratory syncytial virus.

Duration of the treatment - 14 days, number of sessions - 2 per day. We noticed normalization of the condition of the conjunctiva, of the cornea of both eyes, termination of discharge of the pathological character. The result of the treatment was regarded as positive.

15. Diagnosis - purulent infection of skin folds of the claws space. Except from the external disinfection means, the DETA device therapy was used with the following programs:

- Staphylococcus and streptococcus infection,
- Lymph and detox,
- Actinomycosis,
- Dermatomycosis,
- Mycosis of feet and nails,
- Microsporum Kanis,
- Trichophyton basic.

Duration of the treatment - 14 days, number of sessions - 2 per day. On the 4th day of the treatment we noticed decrease of the local inflammation reaction. Healing and cleansing of the tissues was stated after a shorter period of time in comparison with the standard treatment plan.

Tolerance. It is necessary to stress on the good tolerance of the DETA device, absence of general and local adverse reactions during the treatment of the diseases of inflectional and parasitic character. The therapy did not cause negative effect on the duration of the accompanying pathology among the examined patients.

Conclusion.

1. The DETA device (with AP software program) by its functional and operational qualities fully complies with the requirements of the veterinary practice in area of the treatment of diseases of inflectional and parasitic character.

2. The DETA device therapy has showed a high clinical effect both as the monotherapy and in combination with symptomatic treatment in comparison with the traditional treatment methods.

3. No contraindications for using the DETA device in the treatment of animals were identified.

4. The DETA device may be used in hospital, outpatient and domiciliary conditions.

5. Further trials of the device in treatment of different pathologies of small pets is recommended.

Recommendations.

In accordance with all above mentioned, on the basis of the clinical tests we propose to add the DETA antiparasitic device to the instrumental base of veterinary institutions.

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Veterinary physician: Gainedinova G.A. [Signature]

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Protocol of the clinical trial of the effectiveness of the treatment with the DETA device

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Veterinary station of the Ufa city

Vetrinary clinic “Nadezhda”

Head of the veterinary clinic

Muhametzyanov Yanur Rimovich

December 12, 2009

Ufa city

Objective of the trial: To estimate the possibilities of using the DETA device made by LLC Scientific Development and Production Enterprise “ELIS” in the veterinary practice at the territory of Russian Federation on the basis of the Ufa city veterinary station.

Type of the trial: open, comparative.

Objectives of the trial:

1. To determine the clinical effectiveness of using the DETA device during treatment of diseases of small pets of the inflectional and parasitic character as a monotherapy.
2. To study the clinical effectiveness of using the DETA device as a part of the complex treatment of small pets diseases of inflectional and parasitic character.
3. To estimate the safety of using the DETA device during treatment of diseases of small pets of inflectional and parasitic character.

Research plan: conduction of clinical tests at small pets. Collection of the patients is conducted in accordance with the chosen criteria of inclusion.

Criteria of inclusion: cats, dogs, guinea pigs, hamsters, birds were included into the research. Observation and treatment were conducted basing on the informed voluntary consent of the pets’ owners.

Place and time of conduction of the researches:

Kuvykynskaya veterinary clinic of Ufa city veterinary station.

For conduction of the research we were provided with:

1. The DETA device made by LLC Scientific Development and Production Enterprise “ELIS” (Moscow) in the quantity of 1 piece; software program of the device providing antiparasitic therapy.
2. The DETA device approved for the use in medical practice (registration certificate of the

Federal Service on Surveillance in Healthcare and Social Development of the Russian Federation No. __as of___)

3.Operational manual of the DETA device.

4.Methodical recommendations

Method of diagnostic and treatment is protected by the patent No. 2000114578 as of March 20, 2003, legally used by LLC Scientific Development and Production Enterprise “ELIS”.

Results of the research:

Trials of the clinical effectiveness of different ways of correction of the inflectional and parasitic diseases treatment was conducted among 85 patients (42 cats, 35 dogs, 2 guinea pigs, 3 hamsters, 3 wavy parrots) in the age from 4 months to 15 years.

Groups of observation were compatible by sex, age, nosological forms, severity of the main disease and expression of the dysbiotic disorders. Clinical characteristics of the groups of observation is given in Table 1.

Table 1

Diagnosis	Form of the disease	Amount of the patients	Average duration of the treatment with the DETA device
toxoplasmosis	chronical	19	10 days
purulent otitis	chronical	15	5 days
helminth vermitation	chronical	28	5 days
dysbacteriosis	acute	15	5 days
dysbacteriosis	chronical	15	10 days
lambliosis	chronical	30	10 days

Diagnosis	Form of the disease	Average duration of the treatment with the DETA device	Average duration of the medicament treatment (without using the DETA device)	Effectiveness of using the DETA device
toxoplasmosis	chronical	10 days	21 day	80%
purulent otitis	chronical	5 days	14 days	82%
helminth vermitation	chronical	5 days	20 days	85%

dysbacteriosis	acute	5 days	14 days	92%
dysbacteriosis	chronical	10 days	30 days	89%
lambliosis	chronical	10 days	21 day	85%

Treatment method. Before the treatment procedure was conducted the DETA device was prepared for exploitation in accordance with guidance of the device's operational manual. The device was turned on and turn off in accordance with the guidance of this manual. During conduction of the session, the device was located in the close proximity from the patient's body. The procedures lasted for 3-15 minutes, sessions were run 1-2 per day, a course lasted from 5 to 10 days.

Assessment of the therapeutic effectiveness of different treatment methods was conducted on the basis of daily clinical observations, including assessment of the general condition of patients, dynamics of the body's weight, condition of the functionality of the gastrointestinal tract, condition of animals' skin and hair. Among the laboratory tests we have performed analysis of excrements for parasitic worms' eggs, analysis of urine, blood swabs for presence of causative agents of parasitic diseases, luminescent diagnosis, microscopial investigation of skin scrapings. Analysis of the patients' health indexes before and after the treatment was made.

Clinical observations of the patients who received treatment with the device as a monotherapy and as a combined therapy, allowed to identify more vivid positive therapeutic effect in comparison with the control group (which received a standard medical treatment). The effect was expressed by a shorter term of the clinical signs of diseases disappearance.

More specifically: in case of presence of the dyspeptic syndrome at pets of the 2^{nd} and the 3^{rd} groups, we noticed decrease of the number of defecation acts, improvement of excrements consistency happened 2 times faster (at the 4^{th}-5^{th} day respectively) than in the control group (12±2 days). Disappearance of the symptoms of bloating of abdominal among the patients of the 2^{nd} and the 3^{rd} groups was noted on average on the 3^{rd} day (3.9±0.8 and 4.0±0.5), while among the pets who received the medicament treatment, only on the 6th ± 2 day. Termination of the pain syndrome among the patients of the tested groups happened on the 4^{th} day, that is 2 times faster than in the control group. Impact of different ways of correction of dysbiosis of the observed pets

are described in Table 2 and Picture 1.

Table 2. Dynamics of the main clinical symptoms of the sick pets at different ways of correction of dysbiosis

Sympthoms		Groups of patients					
		Group 1		Group 2		Group 3	
		Number	%	Number	%	Number	%
Bloating, pain abdomen, discharge gases	Before the treatment	3	76	3	97	2	85
	After the treatment	3	20	3	17	2	28
Frequent liquid stool of watery consistency	Before the treatment	5	93	5	90	4	84
	After the treatment	5	33	5	16	4	32
Profuse diarrhea with a hearty dash of blood	Before the treatment	3	67	3	72	2	55
	After the treatment	3	49	3	28	2	25

Influence of different ways of correction of dyspepsia phenomenon.

Observation of the general condition of the pets' health before and after the treatment course showed positive shifts in work of the gastrointestinal tract at the control group where the DETA device therapy was used. More specifically, we noticed signs of restoration of positive microflora of the gastrointestinal tract, reduction of the symptoms of dysbiosis with the disturbance of the microflora among the pets of the 2nd and the 3rd groups. Recovery was observed for 76% of the pets who received treatment with the DETA device and for 92% in the group of combined treatment, while in the control group it was seen only at 35%.

2. Assessment of the effectiveness of using the DETA device in treatment of toxoplasmosis of animals

Symptoms		Groups of patients					
		1st group		2nd group		3rd group	
		Quantity	%	Quantity	%	Quantity	%
Dermatitis	Before treatment	3	80	3	80	1	77
	After treatment	3	28	3	10	1	33
Dysorexia	Before treatment	2	89	1	85	1	81
	After treatment	2	2	1	16	1	26
Fertility disorders	Before treatment	3	79	3	84	2	62
	After treatment	3	22	3	16	2	27

Influence of different methods of treatment of taxoplasmosis.

The examination of animals' general condition before and after the treatment showed positive results of the overall health of the control group with application of the device. Thus, for the animals of the 2nd and the 3rd groups, there were noticed signs of decrease of antibody titer and allergic dermal irritations. 82% of animals recovered when treated with the DETA device; 90% – when having combined treatment; and only 47% of the control group animals recovered.

3. Assessment of the DETA device efficacy in treatment of middle ear disease (otopyosis).

Symptoms		Groups of patients					
		1st group		2nd group		3rd group	
		Quantity	%	Quantity	%	Quantity	%
Redness, soreness, puffiness of the external ear and acoustic meatus with insignificant discharge of purulent effluent	Before treatment	2	66	2	89	1	86
	After treatment	2	20	2	18	1	28
Redness, soreness, puffiness of the external ear and acoustic meatus	Before treatment	4	87	4	60	2	85

with profuse discharge of purulent effluent, smelled ichorous	After treatment	4	18	4	13	2	21

Impact of the different methods of otitis treatment.

When examining the overall health of animals before and after the therapy, positive results of improvement of the ear canal state of the control group with the application of the device were noticed. Thus, the animals of the 2nd and the 3rd groups had signs of decrease of external ear and acoustic meatus skin disorders, and termination of purulent discharge from middle ear. The recovery was observed as follows. 82% of animals recovered when treated with the DETA device; 88% – when combined therapy; and only 47% – for the control groups.

4. Efficacy assessment of the DETA device in treatment of animal helminthic vermination.

Symptoms		Groups of patients					
		1st group		2nd group		3rd group	
		Quantity	%	Quantity	%	Quantity	%
Limosis, fragility of hair and lack of shiny coat	Before treatment	4	75	4	98	2	60
	After treatment	4	22	4	8	2	17
Year-round shedding, loss of whiskers, vomiting with undigested food parts, emaciation	Before treatment	5	80	5	78	4	89
	After treatment	5	10	5	4	4	16
Anorexia, dysorexia, emaciation, coming out of helminthes with stool and vomit	Before treatment	2	55	2	84	2	66
	After treatment	2	11	2	7	2	18

Impact of different methods of treating helminthism.

When examining the animal before and after the treatment, there were positive results of improvement of the control group animals' state of health with the device application. Thus, animals of the 2nd and 3rd groups had dramatic decrease of signs of body intoxication; analysis of stool samples showed the decrease of quantity of the detected helminth eggs. The recovery was observed for 75% of animals treated with the DETA device and for the 85% of animals of the group of the combined treatment, while 60% of the control group animals recovered.

5. Efficacy assessment of treating animal giardiasis with the DETA device.

Symptoms		Groups of patients					
		1st group		2nd group		3rd group	
		Quantity	%	Quantity	%	Quantity	%
Capricious appetite, fragility of hair, matted hair	Before treatment	3	80	3	80	1	77
	After treatment	3	28	3	10	1	33
Year-round shedding, skin dryness, frequent vomiting, weight loss	Before treatment	2	89	1	85	1	81
	After treatment	2	2	1	16	1	26
Anorexia, dysorexia, emaciation, deep skin scratches	Before treatment	3	79	3	84	2	62
	After treatment	3	22	3	16	2	27

Impact of the different methods of treating giardiasis.

The examination of the overall animals' health before and after the treatment demonstrated positive results with the improvement of health of the control group animals with the device use. Thus, for the animals of the 2nd and the 3rd groups, there were noted signs of significant decrease of body intoxication; analysis of stool samples showed that quantity of the Giardia cysts had decreased. 75% of the animals treated with the DETA device recovered as follows: 85% of animals that received combined therapy recovered; and only 60% of the control group animals recovered.

Tolerance. It should be noted that, the DETA device therapy is well-tolerated; and there were no general or local side effects when treating infectious and parasitic diseases. Therapy had no negative impact on the development of comorbidity obtained by observed patients.

Conclusions.

1. By its functional and operational qualities, the DETA device (with the 'AP' Software) completely meets the requirements of the veterinary practice of treating infectious and parasitic diseases.
2. Compared to the traditional methods of treatment, higher clinical effect was demonstrated when using the DETA devices as monotherapy or together with expected treatment.
3. No contraindications for using the DETA device for animals were found.
4. The usage of the DETA-AP device is possible in a hospital, on an outpatient basis, and domiciliary.
5. We recommend further study of the DETA device when treating various pathologies of small domestic animals.

Recommendations.

For the foregoing reasons, based on the clinical study we propose to complement the instrumental base of the veterinary institutions with the antiparasitic DETA device.

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