

APPROVED

By the Head Doctor of Municipal Prevention and Treatment Facility Clinical Maternity Hospital No. 4

of City District of Ufa of the Republic of Bashkortostan

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April 14, 2010

(Seal: Municipal Prevention and Treatment Facility Clinical Maternity Hospital No. 4)

Minutes of Clinical Tests to Study the Efficiency of Treatment Applying DETA devices

Test basis: Post-Approval Clinical Testing Agreement dated March 28, 2009.

Test aim: To evaluate the possibilities to apply DETA device manufactured by OOO ELIS Research and Development Enterprise in medical practice on the territory of the Russian Federation in case of gynecological diseases associated with urogenital infections: chlamydia ureaplasmosis, mycoplasmosis, gardnerellosis, candidosis, cytomegalovirus, herpes and toxoplasmosis.

Type of testing: open, non-random, comparative.

Test task:

1. to determine the clinical efficiency of DETA device in case of latent carriage and exacerbation of chronic urogenital infections as sole therapy.
2. to determine the clinical efficiency of DETA therapy in case of acute forms of infectious and inflammatory diseases of genitals, associated with paraveneal infections in the combined treatment
3. To assess the safety of DETA application when treating the above mentioned diseases.

Plan of testing:

Women of reproductive age (18-42 years old) having in-patient treatment in the gynecology department of the City Perinatal Centre were included into the testing.

Patient were selected in accordance with the specified inclusion criteria.

Inclusion criteria: Patients having chlamydia, ureaplasmosis, mycoplasmosis, gardnerellosis, candidosis, cytomegalovirus, herpes and toxoplasmosis infections confirmed by EIA blood analysis and polymerase chain reaction of smears, chronic and acute inflammatory diseases of female genital sphere, having compromised history of miscarriage and infertility, participated in the tests.

Tests and treatment were carried out on the basis of informed voluntary consent of the patient according to the Order No. 163 (Industry-specific Standard (OST) 91500.14.0001-2002) of the Ministry of Health of the Russian Federation. The tests have been agreed with the Ethics Committee.

Time and place of the tests: Gynecology department of Municipal Prevention and Treatment Facility Clinical Maternity Hospital No. 4 of the city of Ufa, from March 2009 till March 2010.

Represented for the tests:

1. DETA-AP and DETA-Ritm devices manufactured by OOO ELIS Research and Development Enterprise (Moscow), 3 item; software of the device provides antiparasitic electromagnetic wave therapy.

2. DETA devices are authorized for application in medicine (Registration certificate of the Federal Service on Surveillance in Healthcare and Social Development of Russian Federation No. FS 022 a1710/4625-06 of December 22, 2009).

3. DETA Manual.

4. Methodological recommendations for application of DETA device.

Diagnosis and treatment methods are covered by patents No. 2000114578 dated March 20, 2003, used by OOO ELIS Research and Development Enterprise on the legal basis.

Test results:

During the period from January 2010 till March 2010 the tests of clinical efficiency of different ways to treat gynecological diseases associated with urogenital infections: Chlamydia, ureaplasmosis, mycoplasmosis, gardnerellosis, candidosis, cytomegalovirus, herpes and toxoplasmosis were conducted among 32 patients (women) being from 18 to 42 years old (average age is 29.4 ± 1.1 years).

The diagnosis of diseases is made clinically and evidenced by immune and enzyme blood analysis and detection of DNA agents paragraphs applying the method of polymerase chain reactions.

The main group was divided into 2 subgroups: the 1st group was treated with DETA devices only, the 2nd group received the combination of drug and bioresonance therapy.

The control group (drug therapy only) consisted of 35 persons (women) being from 18 to 42 years old (average age is 26.3 ± 1.2 years).

The study groups were of similar age, nosological entities and severity of the underlying disease.

Treatment method. DETA-AR device was prepared to the treatment in accordance with the DETA-AR Device Manual. The device was switched on and off in accordance with the instructions of the Manual. During the session the device was located in the projection of the hotbed of disease of the patient. The period of session depended on the individual set of programs, average 40-50 minutes. The frequency is 1-2 sessions per day, depending on the tolerance to the treatment, the course takes from 5 to 10 days.

The necessity of accompanying drug therapy for the main group was determined by the severity of condition of the patients. In case of severe symptoms of intoxication detoxification infusion and antibiotic therapy was conducted for patients with post-natal and post-operative endometritis and infiltrates.

In case of moderate intoxication, mild to moderate disease severity sole bioresonance therapy was conducted.

The efficiency of applied methods is assessed through daily clinical examination, including assessment of the general state of health, thermometry, special gynecological examination, ultrasound 1 time per 3 days, complete blood count determining ESR leukogram, leukocyte index of intoxication. Vagina microbiocenosis before and after the treatment was carried out using light microscopy and bacteriological study.

Clinical monitoring of patients treated by DETA device as the sole therapy and combined with drug treatment, revealed a more pronounced positive effect comparing to the control group receiving antibiotics, infusion and anti-inflammatory therapy.

The efficiency of treatment was expressed by decrease of intoxication (normalization of temperature, Complete Blood Count indices, local status). Elimination of pain among the patients in the main groups took place on the 2nd day, that is 3 times faster than in the control group.

Clinical characteristics of the study groups and the influence of various treatments of pelvic inflammatory diseases are represented in Table 1.

Table 1.

Diagnosis	Number of patients		Average duration of traditional drug therapy in the control group (days)	Average duration of DETA treatment in the main group (days)	Average duration of DETA treatment in combination with the drug treatment in the main group (days)
	Main group	Control group			
Exacerbation of chronic endometritis, salpingo-oophoritis based on the carriage of:	N=16	N=15	10,3±0,4	6,3±0,1	6,0±0,2
• Chlamydia	8	9	9,3±0,2	7,1 ±0,2	6,2 ±0,2
• Ureaplasmosis	7	8	8,2 ±0,3	6,3 ±0,3	6,2 ±0,1
• Mycoplasmosis	9	7	8,2 ±0,4	6,2 ±0,1	6,1 ±0,3
• Cytomegala virus	14	11	10,7 ±0,1	7,1 ±0,1	5,7 ±0,1
• HSV	12	11	11,3±0,2	7,3±0,1	5,9±0,2
Colpitis and cervicitis based on the carriage of:	N=16	N=20	12,3 ±0,7	6,1 ±0,1	Combination therapy was not carried out as there was no need.
• Chlamydia	9	8	11,1 ±0,4	6,3 ±0,2	
• Ureaplasmosis	7	7	11,3 ±0,1	6,1 ±0,2	
• Mycoplasmosis	7	9	10,2 ±0,4	6,2 ±0,1	
• Cytomegala virus	13	11	10,7 ±0,6	7,2±0,1	
• HSV	11	12	12,3 ±0,5	7,1 ±0,1	

Tolerance. It should be noted that DETA therapy is well-tolerated and convenient, there is no general and local adverse reactions when treating gynecological diseases associated with urogenital infections: chlamydia ureaplasmosis, mycoplasmosis, gardnerellosis, candidosis, cytomegalovirus, herpes and toxoplasmosis.

The therapy did not have negative impact on the concomitant somatic pathology of patients. Moreover, the use of DETA-Ritm complex therapy and regenerative frequency provided in antiparasitic programs of DETA-AR device contributes to more rapid restoration of anatomy and function of damaged organs.

Methodological Recommendations.

1. For rapid clinical effect it is recommended to combine the diagnosis and treatment using DETA devices as it leads to categorization of disease agents and determination of optimal frequency of exposure. If there is no such combination the duration of therapy is increased, as the frequencies are determined experimentally.
2. Clinical tests showed that the use of devices even for simultaneous treatment of all considered venereal diseases considered does not cause adverse effects and is tolerated well.
3. Combination of antiparasitic and regenerative programs leads to rapid reduction of acute and chronic inflammatory diseases of female genitals.
4. Frequent treatment methods
 - In case of herpes infection the following programs were used: Herpes basic, Herpes type 1, Herpes type 2 comp, Herpes simplex.
 - In case of chlamydia: Chlamydia general, Chlamydia trachomatis.
 - In case of mycoplasmal infection: Mycoplasma basic.
 - In case of ureaplasmosis: Ureaplasma.
 - In case of toxoplasmosis: Toxoplasma
 - In case of cytomegala virus: Cytomegala virus.

After antiparasitic frequencies the following programs were used: Inflammation of the pelvis, adnexitis, inflammation of the cervix, inflammation of ovaries, regulation of female reproductive system. Treatment duration is 5-10 sessions, up to 2 sessions per day. In most cases the clinical effect was obvious on the 3rd or 4th session of the therapy.

Conclusion.

1. DETA-13 devices (Ritm and AP) regarding its functional and application features fully complied with the requirements of medical practice in treating gynecological diseases.
2. Pronounced clinical efficiency of DETA-13 device is detected as the sole therapy and in combination with drug therapy comparing to traditional treatment methods.
3. There is no contraindication to the use of DETA-13 device among the patients having acute and chronic urogenital infections. The treatment is well-tolerated.
4. DETA-13 device may be used during the hospital and out-patient treatment and at home.

Executive in charge *(Signature)*

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