THE MINISTRY OF HEALTH OF THE RUSSIAN FEDERATION

STATE BUDGETARY EDUCATIONAL INSTITUTION OF HIGH PROFESSIONAL EDUCATION

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Rector of SBEI HPE ISMA

Professor Strelkov N. S.

March 5, 2014

Final report

on clinical approbation of device

"BIOMEDIS-M" of Ltd RPC "BIOMEDIS" (Moscow)

Department of Pediatric Diseases, Neonatology Course of DAT and PU

SBEI HPE “Izhevsk State Medical Academy”

(city Izhevsk, Udmurtia) for 2013-2014 years

Anex №3

to Agreement №3 dated on March 5, 2013

Study of effectiveness of applying bioresonance therapy with the help of the device “BIOMEDIS-M” for children with recurrent diseases of upper respiratory tract (URTI)

1. **Purpose of clinical research:** to study effectiveness and safety of applying the device “BIOMEDIS-M” under conditions of standard post-clinical observation as well as to determine methodical peculiarities of applying the device for administration of bioresonance therapy (BRT) in frequently ill children.

2. **Characteristics of research organization and doctor:**

Department of Pediatric Diseases, Neonatology Course, the Department of the Advanced Training (DAT) and Professional Upgrading (PU) of SBEI HPE “Izhevsk State Medical Academy”.

Head of the Department: Candidate of Medical Sciences, Professor M. B. Colesnicova.

Executor: pediatrician, postgraduate E. A. Lusina.

3. **Duration and stages of research**

Stages: 12 months since the beginning of the treatment course for selected tested persons. Total duration till getting of preliminary results is 2 months; the duration till final results is 6 months.

4. **Quantity of tested persons: 32 persons.**

5. **Criteria for selection of tested persons:**

Criteria for involvement: patients of the ages of 4-5,5 years old with recurrent diseases of upper respiratory tract (5-6 times per year) have been selected for conduct of the research.

Criteria of exclusion:

a) patients with serious dysfunctions of heart, brain, kidneys, lungs, endocrine pathology and metal disorders;

b) patients that have been using antibiotics, immunosuppressive and immunomodulatory drugs during 6 months before examination.

Criteria of exclusion from the research:

Discontinuation of treating procedures without any reason at any moment of applying the course; serious side effects which could hamper conducting further research; appearing of accompanying diseases during study.

6. **Methods of diagnostics:**

- assessment of clinical history;
- objective examination in dynamics;
- examination of ENT in dynamics.

7. **Patients:**

32 children from the group of frequently ill persons with manifestation of chronic media otitis, rhinosinusitis, adenoids and chronic tonsillitis have been examined in dynamics. 22 children have been included in the main group (I). 10 children have been included in the control group (II). The groups have been randomized, depending on sex and age.

8. **Scheme of therapy:** The main group (I) have gotten standard therapy and bioresonance therapy with the device “BIOMEDIS-M”: 3 courses per 10

days. Programs which have been used are following: frequently ill children 1, adenoids, tonsillar hypertrophy, media otitis. The control group (II) has received only standard therapy: anti-viral, anti-bacterial, anti-inflammatory, antihistamine, symptomatic and local ones.

9. Parameters of observation.

Complaints: difficulty breathing through nose, snoring, sniff while sleeping; coughing in morning; changes of voice's timbre; frequent otitis, decreased hearing; frequent rhinitis; irritability, fatigue, sleepiness; impairment of memory and attention.

Syndromes: syndrome of chronic intoxication, astheno-vegetative syndrome, catarrhal syndrome, and lymphoproliferative syndrome.

10. Evaluation of therapeutic effectiveness.

The results of BRT on health of the group (I) in comparison with the control group (II) have been analyzed; the results written below have been achieved. Improvement of health and reduction of intoxication's symptoms in patients of the group (I) have been observed because of impact of BRT by the end of the second month of treatment, while similar results have been observed in patients of the group (II) just by the 4^{th} month of treatment. Frequency of acute respiratory infections in both groups during the period of observation has been statistically unessential but heaviness and duration of one episode of acute respiratory viral infection in children of the group (I) have been lower by 3-5 days. We have noted a reliable difference related to syndrome of chronic intoxication: it has been observed in 30% of children of the group (I), while it has been noted in 70% of those that have received only medical therapy. Frequency of astheno-vegetative syndrome has been detected in both groups similarly: 50% in children of both groups. 50% of children of the group (I) have escaped from the symptoms of difficulty breathing through nose, sniff during sleeping and coughing in morning in 5 months. Only 30% of children of the

group (II) have escaped from these symptoms. Recurrent media otitis has been detected in all patients before the beginning of the treatment. Relapse of media otitis has been observed in 31,8% of tested persons of the group (I) during 6 months of observation, while it has been observed in 60% of the group (II). When it comes to the group (I), decrease of hearing has been noticed in 27,2 % before treatment and in 18,2% after treatment. As for the group (II), decrease of hearing has been in 40% of the tested children before as well as after treatment. Examination of ear, nose and throat has showed that enlargement of adenoids of the 2^{nd} – 3^{rd} sets has been observed in 40,9% of patients in the group (I) before treatment, and enlargement of adenoids of the 1^{st} set has been detected in 59,1% of this group. After 3 courses of treatment adenoids of the 2^{nd} and 3^{rd} sets have remained in 22,7% of the patients. Adenoids of the 2^{nd} and 3^{rd} sets have been detected in 60% of children of the group (I) before treatment, and in 50% of children after treatment. No any patient subjected to BRT has suffered from side effects related to clinical or laboratory parameters.

11. **Conclusions:** Thus, usage of BRT with the help of the device "BIOMEDIS-M" has been effective for complex treatment of children with chronic pathology of upper respiratory diseases (recurrent media otitis, adenoids, sinusitis, tonsils); reduction of exacerbation's duration has been observed in children; no one has had complication. Reduction of adenoids' and tonsils' size (according to conclusions of an ENT specialist) and hearing restoration in children with recurrent otitis are important indicators. The all children have carried on the procedures easily; no one has had adverse reactions or complications. Bioresonance therapy allows reducing stress caused by medicines on patients; it can be recommended to be used in clinical practice.

Head of the Department of Pediatric Diseases, Neonatology Course, Department of DAT and PU, Professor, Candidate of Medical Sciences ***M. B. Colesnicova***

Executor: postgraduate ***E. A. Lusina***