Approved
Deputy Director FGU
Saratov Research Institute
for Traumatology and Orthopedics
with. Professor
D.M. Puchinjan
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«Утверждаю»
Заместитель директора ФГУ
Саратовского научно-
исследовательского института
травматологии и ортопедии Росздрава
доктор медицинских наук, профессор
_____ Д.М. Пучиньян
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Protocol _
On 30 July 2010.
Regarding the implementation of clinical trials
of the device for resonance wave therapy, "Aquvaton"
developed by "Telemak"

During the period 5 October 2009 to July 29, 2010, clinical trials were carried out with the device for resonance wave therapy, "Aquvaton" nr. 00001, developed by the company "Telemak" LLC (Saratov).

1. Purpose and test methods

Aim of the tests - to assess the possibilities of using the device for the treatment of inflammatory and degenerative joint diseases. A randomized, placebo-controlled, double-blind study. All patients signed their consent for participation in this clinical study.

During the clinical study, 50 patients were divided into two groups. The first group consisted of patients with inflammatory diseases of the joints and periarticular tissues - acute posttraumatic arthritis and periarthritis in the large joints.

Criteria for inclusion of patients in the study was traumatic causes of arthritis, acute phase of disease progression. Exclusion criteria were infectious complications of skin and subcutaneous tissue, hemarthrosis, damage to the bone and periarticular tissues.

The second group consisted of patients with degenerative-dystrophic diseases of the large joints (coxarthrosis, gonarthrosis).

Criteria for inclusion were patients developed limitation of joint movement, as well as the formation of painful syndromes. The degree of pain was assessed with visual analogue scale (VAS). Exclusion criteria were osteoarthritis of the hip and knee in grades I and III, infectious complications of skin and subcutaneous tissue.

During the study, patients were placed randomly in two groups: the first group for treatment with Aquaton devicet, the second group was given a placebo. For this purpose two devices was used (no. 1 and no. 2), where unit no. 2 had a blocked generator function.

Randomization was performed using a random number generator. For every group a set of random numbers was generated from 1-50. From position 1-25 in the set, was formed as the first group and the next 2:2 subgroup.

Exposure was carried out with the device from a distance of 20 cm with a magnetic antenna horn for 20 minutes over the intended area. The number of sessions per patient was in average 12 ± second. Treatment with the Aquatone device was performed in mode 2 and in combination with medication. Other forms of physical therapy was not applied.

Statistical analyzes were performed with Statistica 6.0 software. Results are presented as arithmetic means and the error values. Statistically significant differences in the studied parameters were determined using the Chi-square test.

2. Brief technical information

The device for resonance wave therapy, Aquatone, is intended for therapeutic electromagnetic (UHF) therapy. The effects are based on resonance waves in the aquatic environment, according to staff at the IRE RAN, Saratov.

Weight, kg, maximum:
The device exterior dimensions - 0.8;
Generator Module - 0.4;
Antenna - 0.2.
Dimensions, mm, maximum
The device exterior dimensions - 170x170x160
Generator Module - 190x115x40
Antenna - 120x100
RF Bakel - 2000
Processing Frequency - 1000 MHz
Output Power:
Mode 1 to 0.75 μW
Mode 2 1.5 μW
Location 3 -3.0 μW

Classification of the potential risks of use - products with average risk (2a).

Scope - personal and professional use (03). Medical use – physiotherapy (060). Functional - therapy (11), prevention (20), rehabilitation (30).

3. Test Results

No side effects in treatments with the Aquatone device has been reported.

Common complaints from patients with arthritis: pain in the joints, swelling, periarticular tissues, and restricted movement of the affected limb.

During the second day of treatment, showed 65% of the largest group of a significant reduction in pain from 7.8 ± 0.24 to 2.9 ± 0.19 points on the VAS, and in 33% of the placebo group, 8.3 ± 0.24 to 5 6 ± 0.21 points, which was a statistically significant difference ($p = 0.032$). At the same time, it was found that in 50% of the maximum group size tumor visibly reduced and increased mobility (the placebo effect-30%), the differences were characterized by statistically significantly ($p = 0.041$).

After 10 days of treatment of patients in the main group, noted that 87% now completely lacked pain, recovery of limbs with up to 90% of movement in affected limbs compared to the healthy side. In the placebo group, 25% continued restrictions on movement by up to 75% of the movement of healthy limbs.

Common complaints from patients with osteoarthritis, pain, limited movement in joints and unusual noises from the joints during movement.

During the second day of treatment, reduced pain was observed in the largest group with an average of 7.4 ± 0.23 3.2 ± 0.17 points, VAS, in the placebo group 5.3 ± 0.18 points, permanent differences characterized by statistically significant differences ($p = 0.043$).

During the 5th day of treatment, the degree of pain in the main group was reduced to 2.2 ± 0.19, in the placebo group, the values was 3.3 ± 0.16 points according to VAS (the results was not significant, $p = 0,067$).

At the 10th day of treatment, the degree of pain in main group was (1.2 ± 0.11), corresponding effects in the placebo group showed (1.4 ± 0.14). The dynamics of joint mobility were not significantly different between the groups.

4. Reviews

1. In acute arthritis, comprehensive treatment with the Aquatone device in combination with drugs facilitates the reduction of pain symptoms, reduces swelling and restores mobility of the limbs.
2. Use of Aquatone the treatment of arthritis shortens the time for the pain relieving effects. The unit does not substantially affect movement in affected limbs.
3. The use of Aquatone device is safe, with no side effects and is well accepted by patients.
4. The device is reliable, easy to use and provides good ergonomics. No disturbances or mishaps occurred during use.
5. The device is mobile and suitable for use in the bed, offering a small footprint and low weight.

5. Conclusion

The "Aquatone" device made by "Telemak" is recommended as medical practice in treatment of inflammatory and degenerative diseases of the joints.

The device is recommended for serial production.

Responsible doctors and physiotherapists
Highest level
2010-07-30. NOW. Poljak