Clinical and physiological evaluation of the effectiveness and tolerability

of Icoone laser hardware technologies

We suppose that concomitant combination of handpieces RoboSolo and RoboTwins within the same treatment will be highly effective in dealing with gynoid lipodystrophy of second and third degrees of severity and with localized fat deposits . After the completion of the combined program including 10 treatment sessions participants will show the increase in skin tightness and elasticity of the targeted area, the reduction of severe gynoid lipodystrophy, the volume reduction of the treated area, weight loss, great satisfaction with the treatment results. Besides that, we expect that the combination of handpieces will be clinically safe with the screening on the device Multiscan BC-OXi, which allows us to observe the change in body fat mass and increase in microcirculation of the lower limbs of the patients under study.

The goal of this trial:

The evaluation of the role of multi-alveolar stimulation in overweight treatment, in the treatment of such disorders as microcirculation disorder in the lower limbs, extracellular fluid imbalance, excess of visceral fat.

Tasks:

Primary

1. To evaluate clinical effectiveness of the concomitant combination of handpieces RoboSolo and RoboTwins in the treatment of gynoid lipodystrophy of second and third degrees of severity and in the reduction of localized fat deposits.
2. To evaluate clinical effectiveness of the skin tonification of targeted areas by a combination of handpieces RoboSolo and RoboTwins.
3. To evaluate clients' satisfaction with the treatment using a combination of handpieces RoboSolo and RoboTwins.
4. To clinically evaluate the tolerability of the combined treatment.

Secondary

5. To evaluate the change in body fat mass during the course of procedures using the combination of handpieces RoboSolo and RoboTwins
6. To study the change in microcirculation of the lower limbs.

Materials and methods:

Healthy female volunteers.

Inclusion criteria:

- Inclusion criteria:
- Age: 35-50 years old
- Signed informed consent to participate in in this trial
- Understanding of the trial procedure and readiness to comply with specialist's recommendations during one-month trial.
- The presence of gynoid lipodystrophy of second and third degrees of, localized fat deposits, poor turgor and elasticity of targeted tissues.
- BMI<21

Exclusion criteria:

- Gestation, lactation period, ineffective contraceptive method during the period of the trial
- Acute exacerbation of chronic diseases
- Use of any injectable lipolytic drugs in the treated area during 12 months prior to the beginning of the trial
- The presence of resistant substances, including polylactic acid, PMMA, silicone, fat grafts (regardless the time of the implantation)
- Any surgery in the areas that are supposed to be treated
- Planning of any body cosmetic procedures during the period of the trial
- Exclusion of increased exercise during the period of the trial (gym workouts more than twice a week)
- Contagious disease in treated areas
- Acute condition of chronic diseases, including autoimmune diseases
- The presence in the past medical history of serious diseases or systemic uncontrollable diseases (for example, blood-clotting disorder, cardiovascular disease, disease of the genitourinary system, respiratory disease, gastrointestinal disease), malignant tumors or HIV infection
- Participation in any other clinical trial during the period of this trial
  Ten patients took part in this trial, all female aged 35-50 (average value is 41,1), weight (kg) 58-91 (average value is 73), BMI 21,8-32,3 (average value is 25,8), waist circumference 72-108 (average value is 88,1), hip circumference 94-115 (average value is 96), m body fat 13,1-36,4 (medium body fat is 24,6).

Ten patients volunteered to take part in this trial, all female:
Aged 35-50 (average value is 41,1),
Weight (kg) 58-91 (average value is 73 kg),
BMI 21,8-32,3 (average value is 25,8),
Waist circumference 72-108 (average value is 88,1),
Hip circumference 94-115 (average value is 96),
M body fat 13,1-36,4 (medium body fat is 24,6).

Trial model

Researchers decided to develop individual protocols for the treatment sessions based on the wishes and goals of the pateints. The treatment sessions were performed on average twice a week and had a 50-minute duration, which included the mandatory use of one basic program (20 minutes) and three target programs (10 minutes each). The action force was regulated depending on the pateints' sensation of pain, and gradually the action force was increased during the following treatment sessions. All the manipulations were carried out with the to the individual costume/uniform.

Primary trial points:
First visit

- Signing of the informed consent, definition of inclusion / exclusion criteria
- Anthropometric parameters measurement: weight, chest circumference, waist circumference, hip circumference, thigh circumference
- Standardized photographing “before” and “after” with measuring grid in the background
- Performing the treatment using the combination of handpieces RoboTwins and RoboSol in targeted area
- Measurement of body impedance with the device Multiscan BC-OXi.

Second visit (after 2-3 day period)

- Recording of side effects
- Performing again the treatment using the combination of handpieces RoboTwins and RoboSol in targeted area

Third visit (after 2-3 day period)

- Recording of side effects
- Performing again the treatment using the combination of handpieces RoboTwins and RoboSol in targeted area

Forth visit (after 2-3 day period)

- Recording of side effects
- Performing again the treatment using the combination of handpieces RoboTwins and RoboSol in targeted area

Fifth visit (after 2-3 day period)

- Anthropometric parameters measurement: weight, chest circumference, waist circumference, hip circumference, thigh circumference
- Recording of side effects
- Performing again the treatment using the combination of handpieces RoboTwins and RoboSol in targeted area

Sixth visit (after 2-3 day period)

- Recording of side effects
- Performing again the treatment using the combination of handpieces RoboTwins and RoboSol in targeted area

Seventh visit (after 2-3 day period)

- Recording of side effects
- Performing again the treatment using the combination of handpieces RoboTwins and RoboSol in targeted area

Eighth visit (after 2-3 day period)

- Recording of side effects
- Performing again the treatment using the combination of handpieces RoboTwins and RoboSol in targeted area

Ninth visit (after 2-3 day period)

- Recording of side effects
- Performing again the treatment using the combination of handpieces RoboTwins and RoboSol in targeted area

Tenth visit (after 2-3 day period)

- Anthropometric parameters measurement: weight, chest circumference, waist circumference, hip circumference, thigh circumference
- Standardized photographing “before” and “after”
- Measurement of body impedance with the device Multiscan BC-OXi.
- Performing again the treatment using the combination of handpieces RoboTwins and RoboSol in targeted area

Bioimpedansometry with the device Multiscan BC-OXi

The method of electrical conductivity measurement in different tissues of the human body.

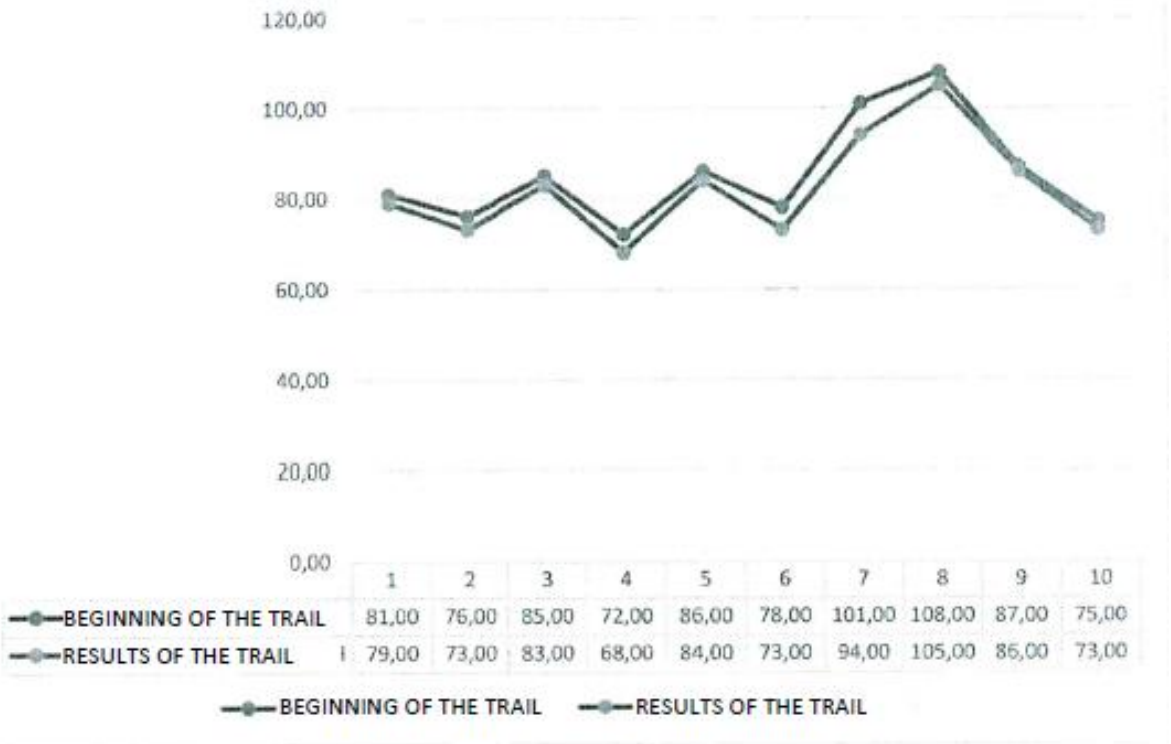
The key potential of bioimpedansometry consists in the following:

- Analysis of the body mass values in terms of ratio between body fat, muscle mass and fat free mass.
- Showing the values of total body water as well as of intracellular and extracellular fluid.
- Evaluation of the values of variable heart rate, stress level and tiredness level, digital analysis of pulse wave.
- 3D-modeling of neuromuscular conductivity of regions of vertebral column, body composition.
- Multifrequency segmental body impedance.
- Measurement of galvanic skin response.

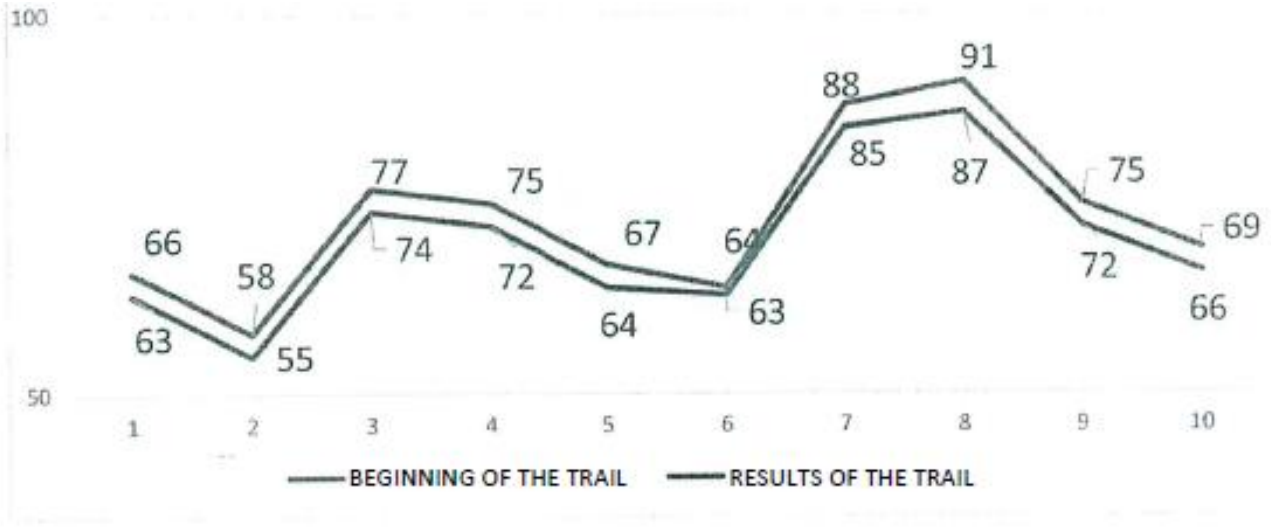
- **Evaluation of effects during periodic examination of patients:**
  When registering the effects during the second visit three patients out of ten had after the treatmnet an increased sensitivity of the skin covering in the areas that were nost intensively treated, which did not represent any pathology and did not lead to further discomfort.
  There were no side effects detected after the treatment sessions.

Results of the trial

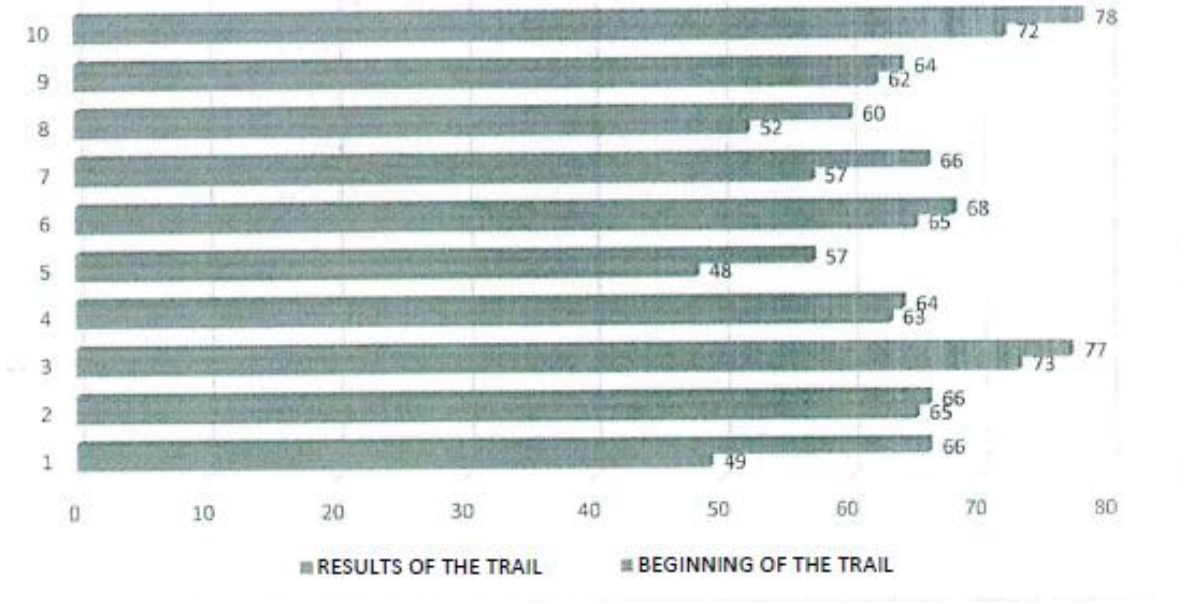
WAIST CIRCUMFERENCE



WEIGHT



Microcirculation in the lower limbs



Results

after the treatment patients experienced the increase in skin tightness and elasticity of the targeted areas, weight loss, reduction od oedema and as a consequence reduction of body volume (waist and hip circumferenec).

When performing bioimpedanceometry with the device Multiscan BC-OXi there was detected the improvement of microcirculation in the lower limbs in all ten volunteers, as well as the reduction of BMI (due to changes in body fat mass).

Consequently, obtained results allow to say that electromechanical fractionalvacuum medical appliance Icoone Laser showed high effectiveness and safety in case of gynoid lipodystrophy of second and third degrees of severity and localized fat deposits, in case of disorders of microcirculation in the lower limbs, and that it constitutes an effective method in body mass correction of skin atony and in the improvement of lymph drainage.

04.07.2018 (stamp and signature) YA.A. Yutskovskaya General director

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