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STEM CELL BRA CLINICAL PROTOCOL

Safety and Efficacy of Bioelectric Stimulation for Breast Augmentation

Sponsor: StemCell Bra, a unit of Leonhardt's Launchpads by Cal-X Stars Business Accelerator, Inc.

Condition To Be Treated: Breast Augmentation

Background:

Many women are interested in increasing the size of their breasts. Currently, the primary treatment involves surgical placement of some type of prosthesis, or fat grafting, with the only non-surgical approach involving injection of stem cell growth factors. The surgical approach has a number of limitations including the need for at least one surgical procedure under general anesthesia, but also the relatively high incidence of leakage or other problems that may require repeat surgery and possible removal of the prosthesis. Other applications for breast augmentation include post mastectomy reconstruction.
A new science-based, and non-invasive approach is the use of micro-current Bioelectric Stimulation, which involves the use of precise micro-current signals delivered to the skin that increase the local tissue expression of a precise number of pro-regenerative proteins or substances that are normally present in the breast tissue, that can stimulate native tissue and specifically glandular structure of the breast by attracting stem cells, enhancing blood flow, and helping to enhance normal tissue growth.

An animal study in sheep demonstrated a 30% increase in breast size after every other day stimulation for one hour for only one month. Ultrasound examination was interpreted as showing normal tissue appearance, with size increase due primarily to increased normal glandular tissue. Only one breast was stimulated, with no effect found in the non-stimulated breast. There were no signs of discomfort in the animal during stimulation.
A second study has been conducted in three different species of cows to assess possible increase in milk production with Bioelectic Stimulation to two teats on one side of the cow utter. These studies showed an average of 15-20% increase in milk production after one month of daily stimulation of the cow utter for 40 minutes/day. These animals also did not exhibit any signs of discomfort during stimulation. Clinical examination of the teats revealed no evidence of inflammation or irritation. Ultrasound examination also showed increase in glandular tissue as the presumed mechanism of increased milk production. Importantly, histologic examination of the utter showed no signs of inflammation or pathologic changes. In addition, the increase in milk production persisted for two months after the stimulation was discontinued.

The bioelectric stimulation in this study will be delivered via a pair of simple gel skin electrodes placed on both sides of each breast, that will then be connected to a stimulator that will deliver the micro-current stimulation at a strength and comfort level that will be selected by each patient. The treatment will take place in your physicians office with twice weekly treatments over a 2 month period. The end point of the study will be both clinical measurement of breast size to assess quantitative enlargement, as well as ultrasound to estimate the change in breast size and confirm the normal appearance and increase in primarily glandular tissue.

Treatment Safety:
The Mettler Bioelectric stimulator to be used in this study has received FDA 510K market approval based on demonstrated safety and efficacy for indications of increasing blood flood flow, wound healing and muscle function.
Bioelectric stimulation at the micro-current levels to be used in this study have been used in many different clinical applications without report of direct adverse effects. A current study is ongoing to examine the possible benefit as a treatment for cancer.

Inclusion Criteria:

1. Age: 21-50 yrs
2. Sex: Female
3. Agree to be present for each of the treatments outline in the protocol.
4. Agree to have de-identified measurements and photos taken of the breast before and after treatment to assess benefit and used to demonstrate the benefit obtained.

Exclusion Criteria:

- Subjects who are pregnant, nursing, planning to become pregnant, and/or not using a reliable form of birth control.
- Subjects who have had prior breast surgery or any therapy for breast augmentation.
- History of breast cancer and treatment with radiation and/or surgery
- Patients who have implantable pacemaker, automatic implantable defibrillator (AICD), or any other implantable electric device.

Treatment Components (To Be Provided by the Sponsor):
Device: Mettler Bioelectric Stimulator and electrodes

Treatment Duration: 30 minutes per treatment

Treatment Schedule: Twice weekly for 30 minutes for a total of 3 months.

Treatment Plan:

Each subject will have small gel electrodes placed on the sides of each breast which will then both be connected to the Bioelectric stimulator. The micro-current strength selected by the subject will be turned on and sustained for a period of 30 minutes.

Breast Ultrasound:
A standard ultrasound of the each breast will be obtained in the first 10 subjects to examine the appearance of the breast tissue and any abnormalities present before and at the end of treatment, with specific assessment of changes in glandular tissue or any structural changes induced by the treatment.

Pre-Treatment Assessment of Tolerability of Bioelectric Stimulation(BES):
Each potential subject will have a test of BES applied to an arm or leg for a period of 20 minutes to simulate a breast treatment and assure tolerability of the treatment. The level of stimulation or current to be used will be selected by each patient during this test and will be the current level used during the course of treatment

Possible Side Effects of Treatment:

There is no history of any skin burn or irritation associated with the use of this low level bioelectric stimulation, and the biologics which will be applied topically to the skin are derivatives of naturally occurring substances and also have no history of allergy, rash, or other adverse reaction. The micro-needling is a common treatment now in use in most aesthetic clinics and has not been associated with pain or adverse effects.

End Points:

Each patient will have a measurement made of breast size before treatment and at the end of 6 weeks and the end of the treatment period of 12 weeks, as well as at 1 and 3 months of follow up after treatment ends.

Primary End Point:
1.Degree of breast enlargement judged by a trained physician who is not involved in the conduct of the trial.
2. The patient's own assessment of degree of breast enlargement and satisfaction graded as no, minimal, moderate, good, or very good improvement. These scores will be kept separate and collated and compared at the end of the study.
Secondary End Points:

1. Any adverse effects thought to be possibly related to this treatment as reported by the subject or noted by the investigator.
2. **Patient satisfaction survey (Appendix A)** which will be completed at the end of the 3 month treatment period, and again at 3 months of follow up.