

February 20, 2019

SKINSTIM CLINICAL PROTOCOL

Safety and Efficacy of Combined Bioelectric Stimulation + Biologic Therapy for the Treatment of Moderate Facial Wrinkles

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

Condition To Be Treated: Facial Wrinkles – Skin Rejuvenation (Non-surgical treatment to tighten facial tissue, collagen stimulation, skin firming & tightening, deep wrinkle reduction, texture improvement)

Background:

The loss of facial skin smoothness, texture, and turgor that can occur with age or other reasons, often leads to the development of unwanted facial wrinkles. Current and previous treatments have been temporary or only somewhat effective in reducing wrinkles.

This multi-component regimen is the most scientifically based and cutting-edge approach to treat facial skin wrinkles. It includes the use of both devices and biologics. The centerpiece is Bioelectric Stimulation, which involves the use of four precise micro-current signals delivered to the skin that increase the local tissue expression of four pro-regenerative proteins or substances that are normally present in the skin, but become depleted with age. These signals will stimulate native skin repair by attracting stem cells, enhancing blood flow, help to rebuild collagen, elasticity and cellular repair.

The bioelectric stimulation will be delivered via electrodes to be worn on the face that will deliver the micro-current at a strength and comfort level that will be selected by each patient. Platelet-Rich Fibrin (PRF), which contains many growth factors to enhance the function of the stem cells mobilized to the skin, and a Regenerative Fluid derived from post-delivery placenta derived stem cells, which contains all the substances needed at birth to form skin and every tissue of the body.

Treatment Safety:

Each of the components of this treatment regimen have received FDA 510K market approval based on demonstrated safety and efficacy. The combination of the components should therefore not cause any adverse interactions, and should be additive in benefit.

Inclusion Criteria:

1. Age: 30-65 years of age
2. Sex: Female or Male
3. Agree to be present for each of the treatments outlined in the protocol

4. Consent of photos taken of treatment areas before and after treatment

Exclusion Criteria:

- Patients who are pregnant, nursing, planning to become pregnant, and/or not using a reliable form of birth control.
- Patients who have had prior exposure to any hyaluronic acid, or any other similar topical agent, in the 2 months preceding study enrollment through the duration of the study.
- Patients who have had prior exposure to any botulinum toxin, or other collagen based product for facial rhytids or in the proposed treatment area in the 4 months preceding study enrollment through the duration of the study.
- Patients who have had a prior cosmetic surgical procedure to improve facial rhytids (i.e., rhytidectomy, periorbital or eyelid/eyebrow surgery, brow lift, CO2/erbium laser resurfacing, Thermage/Coolsculpting, radiofrequency treatment) within 6 months to 1 year or who have visible scars that may affect evaluation of response and/or quality of photography.
- Ablative skin resurfacing on the glabellar area within the previous 6 months or during the study.
- Retinoid, microdermabrasion, or professional or medical grade alpha-hydroxy acid (AHA) treatments within 1 month prior to study participation or during the study. (However, if patient has been on retinoid or any alpha-hydroxy acid as part of their facial regimen we ask that you discontinue it 7 days prior to treatment.)
- Accutane should be discontinued for at least 6 months
- Oral Isotretinon within the past 3 months.
- Active cut, wound, or infection on the face.
- Active HSV-1.
- History of keloids or hypertrophic scarring.
- Existing or history of skin malignancy.
- Any existing facial skin disease.
- History of collagen or vascular disease.
- Patients who have used, within 30 days, any medication that can cause dermal hypersensitivity or affect skin characteristics.
- History of autoimmune disease.
- History of any disease that inhibits pain sensation.

- Bruising from microneedling and injections may occur. Avoid blood thinners, aspirin, anti-inflammatory medications (ibuprofen, Aleve), alcohol, Ginkgo bilboa, vitamin E and fish oil for 5-7 days prior to microneedling to minimize bruising risk.
- Patients who have implantable pacemaker, automatic implantable defibrillator (AICD), or any other implantable electric device.
- If patient is prone to cold sores, they may experience a breakout. Medication can be prescribed.

Treatment Components (To Be Provided by the Sponsor):

1. Devices:

- A. SkinStim Bioelectric Stimulator and electro hand gloves
- B. DermaPen microneedling device
- C. Centrifuge for separation of PRF from plasma in blood sample
- D. Electro hand gloves

2. Biologics

- E. Conductive Gel
- F. Platelet-Rich Fibrin (PRF) supplies needed for centrifuge
- G. Regenerative Fluid from human placenta

Treatment Duration: Each patient will be treated for a total of 3 months with decreasing frequency of clinic visits and treatments.

Treatment Schedule

Bioelectric Stimulation (BES):

Mettler Stimulator

Month 1: Twice weekly for 45 minutes

Months 2 & 3: Once a week for 45 minutes

BES treatment to be done 3-7 days before each microneedling treatment.

Apply conductive gel to the surface of the skin before electrodes placement.

Pre-Treatment Assessment of Tolerability of Bioelectric Stimulation (BES):

Each potential patient will have a test of BES applied to an arm or leg for a period of 5 minutes to simulate a facial 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.

The duration of treatments will be the same for each patient.

Microneedling:

Microneedling treatments at months 1, 2 and 3. After microneedling is completed, the Regenerative Fluid and PRF are injected into problem areas and applied to the surface of the skin.

Platelet-Rich Fibrin:

Obtained from a small sample of patient's blood and prepared on-site via a low speed centrifuge. After completed microneedling treatment, PRF is injected in the problem areas of skin and applied to the surface of skin.

Regenerative Fluid:

This non-manipulated fluid is derived from human placenta cells. After completed microneedling treatment, Regenerative Fluid is injected in the problem areas of skin and applied to the surface of skin.

PRF and Regenerative Fluid should be left on patient's face for a minimum of 6 hours, ideally for 12 hours.

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 microneedling is a common treatment now in use in most aesthetic clinics and has not been associated with pain or adverse effects. Short term sides effects include possible redness, bruising and swelling.

End Points:

Each patient will have photos taken of their face with no makeup applied before and after the treatment period to document the benefit of the therapy. The main end point of the study is the **patient satisfaction survey** which will be completed at the end of the treatment period and at 3 months of follow up.