

July 19, 2020

SKINSTIM REGISTRY EUROPE CLINICAL PROTOCOL

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

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

Condition To Be Treated: Skin Wrinkles, (Face, neck, chest, hands)

Background:

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

The SkinStim multi-component regimen is the most scientifically based and cutting-edge approach to treat skin wrinkles. It includes the use of both devices and biologics. The centerpiece is Bioelectric Stimulation, which involves the use of precise micro-current signals delivered to the skin that increase the local tissue expression of several pro-regenerative proteins or substances that are normally present in the skin, but become depleted with age, such as Klotho and Collagen. Klotho is an important natural anti-aging protein that has significant anti-inflammatory and repairative properties important in tissue regeneration to restore the skin to a younger appearance. These signals will stimulate native skin repair by attracting stem cells, enhancing blood flow, and help to enhance skin elasticity and cellular repair.

The bioelectric stimulation will be delivered via gel patch electrodes to be worn over the face that will deliver the micro-current at a strength and comfort level that will be selected by each patient. This micro-current stimulation will increase the levels of many pro-regenerative proteins that are depleted in your skin and include signals that drive stem cells to your skin, enhance blood flow and cellular repair, enhance skin texture primarily with stimulating collagen production, plus stimulation of a newly identified protein called Klotho, that is a potent anti-aging protein. This treatment can be applied to any area of skin wrinkles not just for the face including neck, upper chest and hands. This controlled use of micro-current causes no injury to your skin or pain.

The biologics to be used include a hydrogel cream that provides important additional enhancement of the texture of the skin, and the use of one of nature's most important pro-regenerative substances, Platelet Rich Fibrin (PRF), which contains many growth factors to enhance the function of the stem cells mobilized to the skin. The Platelet Rich Fibrin will be obtained from a small sample of your own blood, and prepared by simple centrifugation to concentrate the fibrin component of your blood on site in the clinic before you start treatment. It will then be delivered both topically and by injection.

The PRF is injected into the sub-epidermis following application of a lidocaine cream to prevent pain and followed by the newest method of delivering this signals and regenerative biologics into the dermis and sub-epidermis using the new advanced Fractional Microneedling machine applied to any and all desired treatment areas typically before and after delivery of the biologics to aid deeper penetration of these important agents.

All patients will have a very detailed analysis of the quality, texture, and appearance of both the dermis and sub-epidermis using the non-invasive Visia Skin Analyzer. This machine takes photos that will be used as a baseline and then repeated for objective visualization and objective measurement of the anticipated benefit of this therapy.

Inclusion Criteria:

- Age: 30-75 yrs
- Sex: Female or Male
- Willing to attend each of the scheduled treatments
- Presence of moderate facial wrinkles

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 exposure to any hyaluronic acid, or any other filler, injection for any purpose in the 12 months preceding study enrollment through the duration of the study.
- Subjects who have had prior exposure to any botulinum toxin for facial rhytids in the 3 months preceding study enrollment through the duration of the study.
- Subjects who have had a prior cosmetic procedure to improve facial rhytids (i.e., rhytidectomy, periorbital or eyelid/eyebrow surgery, brow lift, CO2/erbium laser resurfacing, Thermage/Thermacool radiofrequency treatment) within 6 months 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 3 months or during the study.
- Retinoid, microdermabrasion, or prescription level glycolic acid treatments within 3 months prior to study participation or during the study.
- Oral Isotretinon within the past 3 months.
- Active cut, wound, or infection on the face.
- History of keloid formation on the skin

- History of keloids or hypertrophic scarring.
- Existing or history of skin malignancy.
- Any existing facial skin disease.
- Patients who have used, within 30 days, any medication that can cause dermal hypersensitivity or affect skin characteristics.
- Current smoking
- Patients who have implantable pacemaker, automatic implantable defibrillator (AICD), or any other implantable electric device.

Treatment Schedule

Length of Treatment: 3 months

Frequency of Treatment: Twice/week for first month, then once/week for 2 months

Duration of Each Treatment: 30 minutes

Total Number of Treatments: 12

Stimulator to be Used: FDA 510K and CE Mark approved Mettler model 240.

Skin Analyzer: Visia, or equivalent

Location of Treatments: All treatments will take place only in the Clinic of the Investigator approved for participation in this study

Treatment by Individual Components:

Visia Skin Analyzer: This non-invasive imaging of the skin area to be treated will be obtained at the start and conclusion of treatment for detailed analysis of the skin.

Bioelectric Stimulation: Delivered by an FDA approved Mettler 240 stimulator

Month 1: Twice weekly for 30 minutes

Months 2&3: Once/week for 30 minutes

Fractional Microneedling: This will be performed before and after application of PRF and exosomes to enhance fluid penetration in the treatment areas.

Platelet Rich Fibrin:

This substance is obtained from a small sample of patient's blood and prepared on-site by low speed centrifuge. It is first massaged topically into the skin and then Injected via Fractional Microneedling into the targeted area of skin.

Treatments: (3). Baseline pre-treatment, then at months 2 &3 of treatment.

Hydrogel Cream:

This will be applied topically and massaged into the area to be treated after each of the bioelectric stimulation treatments.

Possible Side Effects of Treatment:

The strength of the micro-current bioelectric stimulation will be adjusted to a comfort level selected by each patient. The duration of treatments will be the same for each patient.

There is no history of skin burn or irritation associated with the controlled use of this low level bioelectric stimulation, and the biologics which will be injected or applied to the skin are derivatives of naturally occurring substances and also have no history of allergy, rash, or other adverse reaction.

Deidentified Photos:

Each patient will have consented to have deidentified photos taken of their face using the Visia Skin Analyzer from the front and side with no makeup applied before and at the end treatment to document the benefit of the therapy. Eyes will be blacked out where possible to limit facial recognition.

Patient Self-Assessment:

Each patient will complete a self-assessment at the end of treatment to describe their level of satisfaction with the results of the treatment.

Data Analysis:

Each patient will agree to have the data from their treatment submitted for analysis and potential publication. All patients will be assigned a study number which will be used for all data analysis to prevent any patient identification. The data will be analyzed by a statistician not involved in the study. A plastic surgeon not involved with the study will separately grade the level of change and improvement in the treated skin.

Equipment Needed for Study Execution:

1. Mettler 240 Bioelectric Stimulator
2. Bio-PRF Centrifuge Machine
3. Visia Skin Analyzer or its equivalent
4. Fractional Microneedling machine
5. Hydrogel Cream
6. Gel based patch skin electrodes or facial mask