Clinical Evaluation of the Efficacy of Fractional Radiofrequency for the Treatment and Reduction of Stretch Marks

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1 OBJECTIVES AND PURPOSE

The study is being conducted to evaluate the safety and performance of fractional RF for the treatment and revision of stretch marks. Total expected duration of the clinical investigation is ten months (enrolment period of 2 months, study participation period of 8 months), while individual subject participation will take 8 months.

2 STUDY DESIGN AND ENDPOINTS

2.1 DESCRIPTION OF THE STUDY DESIGN

This is a prospective, single centre, evaluator-blind study of the performance of fractional radiofrequency (RF) for the treatment and revision of stretch marks.

2.1.1 PRIMARY ENDPOINT

•Objective volumetric evaluation of striae via Antera 3D Imaging System Analysis at 12 and 16 weeks post-final treatment
• Improvement in the appearance of stretch marks at 12 weeks and 16 weeks post-treatment compared to baseline as assessed by investigator and blinded evaluators by photographic assessment utilizing the Global Aesthetic Improvement Scale (GAIS)

2.1.2 SECONDARY PERFORMANCE ENDPOINTS

• Improvement in the appearance of stretch marks at 12 weeks and 16 weeks post-treatment compared to baseline as assessed by investigator utilizing the Modified Manchester Scar Scale (MSS)
• Subjects' assessment of satisfaction with the treatment using a Subject Satisfaction Scale at 12 weeks and 16 weeks post-treatment.

2.1.3 SAFETY ENDPOINTS

• Subject's assessment of discomfort and pain after treatments as measured by a 10 cm visual analog scale (VAS) and Tolerability Scale

• Subjects experiencing a treatment-related adverse event (AE) by 16 weeks post-treatment.

3 STUDY ENROLLMENT AND WITHDRAWAL

3.1 STUDY POPULATION

The study will enroll male and female adult subjects requesting fractional radiofrequency treatment of stretch marks until 15 subjects have been treated according to the study protocol.

3.2 PARTICIPANT INCLUSION CRITERIA

1. Healthy, male or female subjects, 18-60 years of age who are seeking treatment for their stretch marks
2. Fitzpatrick skin type I-IV
3. Able to read, understand and voluntarily provide written Informed Consent.
4. Able and willing to comply with the treatment/follow-up schedule and requirements.

3.3 PARTICIPANT EXCLUSION CRITERIA

1. Pacemaker or internal defibrillator, or any other active electrical implant anywhere in the body (e.g. cochlear implant).
2. Subjects with any implantable metal device in the treatment area
3. Permanent implant in the treated area, such as metal plates and screws (excluding dental implants), or an injected chemical substance.
4. Current or history of any kind of cancer, or dysplastic nevi in the treated area.
5. Severe concurrent conditions, such as cardiac disorders.
6. Impaired immune system due to immunosuppressive diseases, such as AIDS and HIV, or use of immunosuppressive medications.
7. History of diseases stimulated by heat, such as recurrent herpes simplex in the treatment area; may be enrolled only following a prophylactic regime.
8. Poorly controlled endocrine disorders, such as diabetes.
9. Any active condition in the treatment area, such as sores, psoriasis, eczema, and rash.
10. History of skin disorders, such as keloids, abnormal wound healing, as well as very dry and fragile skin.
11. History of bleeding coagulopathies, or use of anticoagulants.
12. Use of isotretinoin (Accutane®) or other systemic retinoids limited up to 10mg/day or as per investigators discretion.
13. Treating over tattoo or permanent makeup.
14. Excessively tanned skin from sun, tanning beds or tanning creams within the last two weeks.

3.4 PARTICIPANT WITHDRAWAL OR TERMINATION

3.4.1 REASONS FOR WITHDRAWAL OR TERMINATION

Subjects are free to withdraw from participation in the study without prejudice at any time upon request.

The investigator may terminate participation in the study if:

- Any clinical adverse event (AE), laboratory abnormality, or other medical condition or situation occurs such that continued participation in the study would not be in the best interest of the subject.
- The subject meets an exclusion criterion (either newly developed or not previously recognized) that precludes further study participation.

3.4.2 PREMATURE TERMINATION OR SUSPENSION OF STUDY

The principal investigator or regulatory authority may suspend or prematurely terminate participation in the study at the investigation site for which they are responsible.

4 INVESTIGATIONAL DEVICE

4.1 INVESTIGATIONAL DEVICE AND CONTROL DESCRIPTION

4.1.2 DEVICE SPECIFIC CONSIDERATIONS

- Device model(s): Venus Viva™
- Device settings and programming: Ablation or Coagulation Mode; 180-280 volts, 5-30 ms pulse duration
- Duration of exposure and frequency: Multiple passes, 4 treatments, roughly 4-6 weeks apart, multiple treatment areas per subject may be treated. Treatment area size – 3”x3”or smaller

4.3 STUDY SCHEDULE

4.3.1 SCREENING

Visit 1, Screening Visit
(Day -14 to 0)

Informed consent will be obtained from the subject prior to any study procedure, clearly indicating his/her understanding of the requirements and possible risks associated with study participation and other applicable treatment options.

Subject will be screened for eligibility to participate in the clinical study using the inclusion/exclusion criteria. During screening, the study doctor will review the subject's medical/surgical history, demographics and examine the subject's targeted area to ensure that it meets the study criteria.

4.3.2 ENROLLMENT/BASELINE/TREATMENT VISITS

Visit 2 – Enrollment/Baseline/Treatment 1 Visit (Day 0)

The investigator will confirm that the subject still meets the inclusion/exclusion criteria. This Baseline visit includes the first of the four treatments. In addition to the treatment, concomitant medications, photographs and the pain VAS and Tolerability Scale are to be completed by the patient. Investigator to assess immediate and short term response and complete a Modifed Manchester Scar Scale (MSS) assessment.

Photographs will be taken prior to first treatment and throughout the study according to specified time points detailed in the Schedule of Events Table utilizing the Antera 3D Imaging System.

A topical anesthetic may be prescribed and applied to the treatment site prior to treatment at the investigator's discretion. The parameters may be modified during subsequent visits, as per the practitioner's discretion.

The investigator will examine the treated areas and report immediate and short term response (20-30 minutes post-treatment) using a 5-point scale. The assessment of discomfort/pain based on the subject's completion of the 10 cm VAS should also be documented immediately after each treatment.

Visit 3 – Treatment 2 - Week 4 (+/- 7 days)
The Subject is to return to the clinic for their second treatment. In addition to the treatment, concomitant medications, photographs, AEs and the pain VAS and Tolerability Scale are to be completed by the patient. Investigator to assess immediate and short term response.

Visit 4 – Treatment 3 - Week 8 (+/- 7 days)
The Subject is to return to the clinic for the third treatment. In addition to the treatment, concomitant medications, photographs, AEs and the pain VAS and Tolerability Scale are to be completed by the patient. Investigator to assess immediate and short term response.

Visit 5 – Treatment 4 - Week 12 (+/- 7 days)
The Subject is to return to the clinic for the fourth and final treatment. In addition to the treatment, concomitant medications, photographs, AEs and the pain VAS and Tolerability Scale are to be completed by the patient. Investigator to assess immediate and short term response.

4.3.3 FOLLOW-UP

Visit 6 – 12 Week Follow Up Post Final Treatment (+/- 7 days)
Subjects will return to the clinic 12 weeks after the final treatment. Adverse events, and any changes to concomitant medications will be recorded. Subjects will complete a Patient Satisfaction questionnaire. Investigator to complete a Global Aesthetic Improvement Scale (GAIS) and Modified MSS assessment. Photographs of the treated area will be taken.

Visit 7 – 16 Week Follow Up Post Final Treatment (+/- 7 days)

Subjects will return to the clinic for a final study visit 16 weeks after the final treatment. Adverse events, and any changes to concomitant medications will be recorded. Subjects will complete a Patient Satisfaction questionnaire. Investigator to complete a GAIS and Modified MSS assessment.

Photographs of the treated area will be taken.

The termination form will be completed, and subjects will be terminated from the study. The PI will record all reportable events with start dates occurring any time after informed consent is obtained until 7 (for non-serious AEs) or 30 days (for SAEs) after the last day of study participation.

5 ETHICS/PROTECTION OF HUMAN SUBJECTS

5.1 ETHICAL STANDARD

The investigator will ensure that this study is conducted in full conformity with the latest version of the Declaration of Helsinki (2013), ISO 14155:2011 and any other applicable country's ethical policy statement.

5.2 INFORMED CONSENT PROCESS

5.2.1 CONSENT/ASSENT AND OTHER INFORMATIONAL DOCUMENTS PROVIDED TO PARTICIPANTS

Informed consent is required for all subjects in a study. In obtaining and documenting informed consent, the investigator should comply with applicable regulatory requirements and should adhere to ISO 14155:2011 and to the latest version of the Declaration of Helsinki (2013).

5.2.2 CONSENT PROCEDURES AND DOCUMENTATION

Participants will have the opportunity to carefully review the written consent form and ask questions prior to signing. The participant will sign the informed consent document prior to any procedures being done specifically for the study. The participants may withdraw consent at any time throughout the course of the trial. A copy of the informed consent document will be given to the participants for their records. The rights and welfare of the participants will be protected by emphasizing to them that the quality of their medical care will not be adversely affected if they decline to participate in this study.

5.3 PARTICIPANT AND DATA CONFIDENTIALITY

The study protocol, documentation, data, and all other information generated will be held in strict confidence by the participating investigators, their staff, and their agents.

Study participant research data, which is for purposes of statistical analysis and scientific reporting, will be transmitted to and stored at the Investigator's office. Individual participants and their research data will be identified by a unique study identification number. At the end of the study, all study databases will be de-identified and archived by the investigator.