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The PREFORM Study: An Exploratory, Single-Center Study to Evaluate the Safety and Efficacy of Rotational Fractional Resection on Submental Contouring and Optimal Peri-Procedure Regimen for Accelerated Recovery

Protocol Number:	CLP-0007
Version	17-May-2019, Amendment 1
Name of Investigational Product:	Recros Medica Focal Contouring System
Sponsor:	Recros Medica, Inc. 3525 Del Mar Heights Road, Suite 609 San Diego, CA 92130a
Emergency Telephone Number(s):	714-309-7667
Serious Adverse Event Reporting:	rmcintosh@recrosmedica.com
Recros Medica Safety Physician:	Catherine Kusnick, MD
Recros Medica Signatory:	Robin McIntosh
NCT Number:	NCT03966924

Investigational Device:

Recros Medica Focal Contouring System to perform Rotational Fractional Resection (skin resection with and without and focal lipectomy)

Study Objective:

The objective is to explore and evaluate the peri-procedure treatment plan for accelerated recovery after Rotational Fractional Resection in patients with submental laxity.

Study Design

Structure: Prospective, single-center, exploratory, interventional cohort, non-significant risk (NSR) study.

Duration: Approximately 4 months for each subject from the screening visit to the exit visit.

Visit Schedule: Screening, procedure, Day 1, 4, 7, 14, 21, 30, 45, 60, and 90 post-procedure. An optional visit may occur 5-6 days after procedure.

Indication for Use: The Recros Medica focal contouring system is intended for resecting skin with and without fat removal for the purpose of submental contouring.

Study Population Characteristics

Number of Subjects: Up to approximately 50 subjects will be enrolled (consented) to ensure up to approximately 30 subjects treated at 1 US site.

Condition/Disease: Adult subjects with moderate to severe submental laxity.

Key Inclusion Criteria: Healthy male or female, at least 30 years old; moderate to severe submental laxity; agree to maintain weight (±5%) for the duration of the study

Key Exclusion Criteria: History of psoriasis, hyperpigmentation, eczema, rosacea or vitiligo; history of keloids, hypertrophic scarring, or other skin condition that may result in excessive scarring; Fitzpatrick skin type 4, 5, and 6; severe or very severe lipodystrophy; body mass index >30 kg/m^2; treatment with aspirin or aspirin containing products (e.g., Excedrin), NSAIDS, vitamin E within 14 days of the procedure.

Response Measures

Efficacy:

- Submental Skin Laxity Scale, as assessed by the investigator
- Submental Lipodystrophy Scale, as assessed by the investigator
- Subject Satisfaction Questionnaire, as assessed by the subjects

Safety:

- Visual Skin Assessment in the procedure area, as assessed by the investigator
- Visual Skin Assessment in procedure area by the subject
- Adverse events
- Manchester Scar Scale
- Visible scarring
- Pain assessment, using an 11-point Numeric Rating Scale (0 to 10), as assessed by the subject
- Vital signs (blood pressure and pulse rate)

Other:

- Peri-procedure interventions
- Elastic Adhesive Membrane Questionnaire
- Weight
- Photography

Sample Size Calculation and Analysis Methods:

Because this study is exploratory in nature, no sample size estimates have been performed.