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The CONFORM Study: A Multi-Center Study to Evaluate the Safety and Efficacy of Rotational Fractional Resection on Submental Contouring

Protocol Number:	CLP-0002
Version	18-October-2018 (Amendment 3)
Name of Investigational Product:	Recros Medica Focal Contouring System
Sponsor:	Recros Medica, Inc. 3525 Del Mar Heights Road, Suite 609 San Diego, CA 92130a
NCT Number	NCT03407313

Investigational Device:

Recros Medica Focal Contouring System to perform Rotational Fractional Resection (skin resection and focal lipectomy)

Study Objective:

The objective is to evaluate the efficacy and safety of using Rotational Fractional Resection in improving submental contouring.

Clinical Hypotheses:

Primary Efficacy:

Removal of skin and fat using Rotational Fractional Resection will result in a noticeable improvement of submental contour, as determined by a mean 0.75 grade improvement on either the Submental Skin Laxity Scale or Submental Lipodystrophy Scale.

Primary Safety:

Post-procedure scarring will be assessed using the Manchester Scar Scale.

Study Design

Structure: Prospective, multi-center, single-arm (non-randomized), interventional cohort, non-significant risk (NSR) study

Duration: Approximately 7 months for each subject from the screening visit to the exit visit.

Visit Schedule: Screening, procedure, Day 1, 7, 14, 30, 90 and 180 post-procedure.

Indication for Use: The Recros Medica focal contouring system is intended for resecting skin and removing fat for the purpose of focal aesthetic contouring of the submentum.

Study Population Characteristics

Number of Subjects: Up to approximately 110 subjects will be enrolled into this study to ensure up to approximately 70 subjects treated at approximately 4-8 investigational sites in the US to ensure that there are at least 55 evaluable subjects.

Condition/Disease: Adult subjects with mild to moderate submental fat and mild to moderate submental skin laxity.

Key Inclusion Criteria: Healthy male or female, at least 30 years old; mild to moderate submental lipodystrophy; mild to moderate submental skin laxity; Fitzpatrick skin phototype 1, 2 or 3; agree to maintain weight (5%) for the duration of the study

Key Exclusion Criteria: History of any intervention to treat submental fat or skin laxity (e.g., liposuction, surgery, chemical lipolysis, cryolipolysis); history of psoriasis, hyperpigmentation, eczema, rosacea or vitiligo; history of keloids, hypertrophic scarring, or other skin condition that may result in excessive scarring; history of folliculitis in hirsute areas; 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

Primary Efficacy:

- Submental Skin Laxity Scale, as assessed by independent raters
- Submental Lipodystrophy Scale, as assessed by independent raters

Secondary Efficacy:

- Submental Skin Laxity Scale, as assessed by the investigator
- Submental Lipodystrophy Scale, as assessed by the investigator
- Subjects with at least a 1-point improvement on the Submental Skin Laxity or Lipodystrophy Scales, as assessed by independent raters
- Subject Satisfaction Questionnaire, as assessed by the subjects
- Image Analysis (IA) of facial photography for skin laxity
- Pre- and post-procedure photography comparison, as assessed by independent raters

Primary Safety:

- Manchester Scar Scale

Secondary Safety:

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

Sample Size Calculation and Analysis Methods:

The sample size calculation is based on two t-tests of the hypotheses for the primary efficacy endpoints. One endpoint is the change in the Skin Laxity Scale from baseline to 90 days; the other is the change in the Skin Lipodystrophy Scale from baseline to 90 days. The null hypotheses are that there is no change in the scale scores. The alternative hypotheses is that there is a change of at least 0.75 points on at least one scale. The endpoint is a composite endpoint of the two, with the requirement for passing the Primary Efficacy Hypothesis that at least one of the null hypotheses be rejected.

Assuming that the true change is 1.0 points on each test, and that the standard deviation (SD) is 0.7 points, the sample size required for combined power of 91% and Type 1 error of 5% is 55. The sample size calculation was done with PASS 14[1] for an inequality test of one mean.

To accommodate approximately 10% attrition, the number of subjects undergoing the procedure will be $55/.9 \approx 60$.

[1] PASS 14 Power Analysis and Sample Size Software (2015). NCSS, LLC. Kaysville, Utah, USA, ncss.com/software/pass.