Baseline Controlled Study to Evaluate the Safety and Efficacy of Combined EMS and RF Treatments for Non-Invasive Circumference Reduction and Skin Tightening

Protocol No: DO608715A, Rev. 02

Date:
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Study Name: **Baseline Controlled Study to Evaluate the Safety and Efficacy of Combined EMS and RF Treatments for Non-Invasive Circumference Reduction and Skin Tightening**

Protocol No.: DO608715A

Revision No.:

Sponsor: **InMode Ltd.**

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1. Protocol Synopsis

Study Title	Baseline Controlled Study to Evaluate the Safety and Efficacy of Combined EMS and RF Treatments for Non-Invasive Circumference Reduction and Skin Tightening
Protocol No	DO608715A, Rev. 02
Sponsor	InMode Ltd.
Investigational Product	Evolve (InMode EmBody System) with Tite (Embody Plus Handpiece K183450) and Tone Applicators
Study Design	Prospective, open label clinical study.
Study Sites	Dr. Chia Dr. Dayan
Patient Population and Sample Size	Subjects aged 18-65, healthy adults, seeking for non-invasive abdominal circumference reduction and skin tightening, male and females. Approximately 20 healthy adult volunteers (10 per site), seeking for non-invasive abdominal circumference reduction, male and females, 18 to 65 years of age from up to 2 investigational sites.
Study Duration	Eligible subjects will receive up to 3 bi-weekly treatments (once in 2 weeks) with the Evolve device utilizing the Tite and Tone applicators according to the study protocol. Study duration for each subject is approximately 8 months (including screening, up to three treatments and 3 follow-up visits at 1 months, 3 months and 6 months post last treatment. Overall study duration will be approximately 14 months, depending on the subject recruitment rate.
Primary Objectives	The objective of this trial is to evaluate the safety and efficacy of the Evolve device utilizing the Tite and Tone applicators for abdominal non-invasive circumference reduction and skin tightening
Secondary Objective	The secondary objective of this study is subject satisfaction, as measured with a self-assessment questionnaire and a rating of device and procedure related adverse events.

Endpoints	***Primary Effectiveness Endpoint:*** 1. The primary efficacy endpoint in this trial is the statistical difference of circumference reduction between Control (baseline measurement) and three points of follow-up measurement: 4 weeks (1Month) 12 weeks (3Month) and 24 weeks (6 months) following the last Tx session. The primary effectiveness endpoint will be calculated based on those patients whose weight remains stable during the study period. A subject is defined as having maintained her weight during the treatment period if it remained within ±3% (inclusive) of baseline for the respective period. 2. Improvement in in skin appearance comparing pre and at 1, 3 months and 6 months post last treatment photographs (as assessed by blinded investigators): - Success is defined by correct identification of the pre and post treatment photos as demonstrated in at least 70% or greater of patients completed the treatment at 1 month, 3 months and 6 months post treatment. - At least 2 out of 3 blinded evaluators should agree on the assessment. 3. Optional: 3D Photographic analysis will be conducted using QuantifiCare System at 1 month, 3 months and 6 months follow up visits and compared to the baseline. 4. Investigator assessment of the skin appearance improvement comparing pre and post treatment using 0 - 4 -points Likert scale at 1 month, 3 months and 6 months follow up visits: 4 = Significantly marked improvement; 3 = Marked improvement; 2 = Moderate improvement; 1 = Slight improvement; 0 = No difference ***Primary Safety Endpoint*** Safety Endpoint Rate of all device and procedure related adverse events (AE's) and serious adverse events (SAE's) occurring during the study. ***Secondary Effectiveness Endpoints:*** Subject satisfaction and comfort: • Improvement assessment will be performed independently by the subject himself using 4 points Likert scale questionnaire (Global Aesthetic Improvement Scale), as follows: - 4 = Significantly marked improvement; 3 = Marked improvement; 2 = Moderate improvement; 1 = Slight improvement; 0 = No difference. • Subject assessment of satisfaction will be filled out by subjects using a 5-points Likert scale, as follows: - +2 = Very satisfied; +1 = Satisfied; 0 = Indifferent; -1 = Disappointed; -2 = Very disappointed.

	• Subject assessment of comfort will be filled out by subjects using a 5-point Likert scale, as follows: - +2 = Very comfortable; +1 = Comfortable; 0 = Indifferent; -1 = uncomfortable; -2 = Pain.

Statement of Compliance

This study will be conducted in accordance with the Code of Federal Regulations on the Protection of Human Subjects (45 CFR Part 46), any other applicable US government research regulations, and institutional research policies and procedures. The Principal Investigator will assure that no deviation from, or changes to the protocol will take place without prior agreement from the sponsor and documented approval from the Institutional Review Board (IRB), except where necessary to eliminate an immediate hazard(s) to the trial participants.

2. Data analysis

9.1 Analysis Sets

- Safety Analysis Set

The safety analysis set will include all subjects using Embrace procedures at least a single time.

- Performance Analysis Set

Performance analysis set will consist of all subjects providing at least one post treatment performance measurement.

- Treatment of Missing Values

Only observed data will be used; i.e. missing data will not be imputed.

9.2 Statistical Analysis

Means, and standard deviations for each characteristic will be calculated. Paired sample t-test will be computed to assess changes in before treatment and follow-up scores. Statistical significance will be calculated and two-tail significance level of 0.05 will be used. All analyses will be conducted using IBM SPSS 21.0.