Clinical Study Protocol

Protocol ID: JS/SG/DN-01

Version: 1.1 (Amended for clarity and structure)

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Title: Effectiveness of Sequential Monopolar and Bipolar Radiofrequency Device for Facial Rejuvenation in Female Participants

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1. Abbreviations

AE – Adverse Event
ADE – Adverse Device Event
CRF – Case Report Form
GCP – Good Clinical Practice
ICF – Informed Consent Form
PI – Principal Investigator
RF – Radiofrequency
SAE – Serious Adverse Event
SADE – Serious Adverse Device Event

2. General Information

Sponsor: Jeisys Medical Inc., Seoul, South Korea
Principal Investigator: Dr. Sylvia Ramirez
Study Centre: Cutis Medical Laser Clinic Pte Ltd, Singapore

3. Protocol Summary

Design: Baseline-controlled, single-arm, prospective clinical study
Duration: Approx. 3 months per participant
Sample Size: 12 female participants, aged 25–60 years
Device: Jeisys Density RF device
Visits: Screening & Baseline/Treatment (Day 1), Follow-up (Day 30), Final Follow-up (Day 90)

4. Introduction

Skin aging leads to loss of collagen and elastin, resulting in wrinkles, laxity, and enlarged pores. Radiofrequency devices offer a non-surgical approach to stimulate neocollagenesis and tissue remodeling. The Density device uses sequential monopolar and bipolar RF modes to target different skin layers safely. This study evaluates its safety and effectiveness in Asian women.

5. Study Objectives and Endpoints

Primary Objectives:
- Evaluate changes in texture, pore size, and volumetric outcomes using AURA 3D imaging.
- Assess participant-reported outcomes with FACE-Q (appearance, quality of life, adverse effects).

Secondary Objectives:
- Assess physician Global Aesthetic Improvement Scale (GAIS).
- Assess changes in Skin Laxity Scale.

Safety Objectives:
- Evaluate safety and tolerability of the Density procedure by monitoring AEs, ADEs, SAEs, and SADEs.

6. Study Design

This is a baseline-controlled, single-arm, prospective study.
- Visit 1: Screening, Baseline, Treatment (Day 1)
- Visit 2: Follow-up (Day 30 ± 5 days)
- Visit 3: Final Follow-up (Day 90 ± 5 days)

7. Study Population

Inclusion Criteria:
- Female, 25–60 years
- Fitzpatrick I–III
- Skin laxity Grade 1–2 (Skin Laxity Scale)
- Able to provide informed consent and comply with visits

Exclusion Criteria:
- Active skin disease, prior facial treatments in past 6 months
- Pregnancy or nursing
- Significant systemic illness
- Known keloid tendency or implant near treatment area

8. Study Device

Device: Jeisys Density RF
Mode: Monopolar and Bipolar RF
Frequency: 6.78 MHz
Tips: Classic-F, High-F
Safety: Neutral electrode used during monopolar mode

9. Informed Consent and Ethics

The study will be conducted in compliance with ICH-GCP, ISO 14155, and the Declaration of Helsinki. Written informed consent will be obtained before participation. Ethics approval will be secured prior to enrollment.

10. Study Assessments

Assessments include:
- FACE-Q questionnaire (baseline, Day 30, Day 90)
- AURA 3D imaging (baseline, Day 30, Day 90)
- Skin Laxity Scale and GAIS (baseline, Day 30, Day 90)
- Pain and tolerability (immediate post-treatment)
- Safety: AE, ADE, SAE, SADE reporting

11. Safety Assessments

Expected reactions include redness, swelling, and mild discomfort. These are generally transient. SAEs will be reported within 24 hours.

12. Study Termination

The study may be terminated early due to safety concerns, high dropout rates, or sponsor/ethics committee decision.

13. Data Management

All study data will be recorded in source documents and CRFs, then transferred to electronic databases. Data will be retained for 10–30 years per sponsor requirements.

14. Statistical Methods

This is a pilot study. Descriptive statistics will be applied. Changes will be analyzed with paired tests (t-test or non-parametric equivalent). Significance set at $p<0.05$.

15. Quality Control and Assurance

Monitoring will be conducted to ensure compliance with GCP. Deviations will be documented and reported.

16. Finance and Insurance

Participants are covered for device-related injury under insurance. No monetary compensation will be provided for unrelated events.

17. Publication Policy

Results may be published with sponsor approval while maintaining participant confidentiality.

18. References

ISO 14155:2020
ICH-GCP E6(R2)

19. Appendices

Appendix 1 – Health Screening Form
Appendix 2 – Dermatological Visual Assessments
Appendix 3 – Participant Questionnaires (FACE-Q)
Appendix 4 – Skin Laxity Scale
Appendix 5 – Site Application Reaction Form
Appendix 6 – Device Technical Details
Appendix 7 – Participant Instructions