Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Jun 2026

Safety and efficacy evaluation of "facial microknife" and "microhook" of Ignite radio hybrid microknife device, made by Medaria company in rejuvenation and improvement of facial sagging symptoms

Protocol summary

Study aim

Safety and efficacy evaluation of "facial microknife" and "microhook" of Ignite radio hybrid microknife device, made by Medaria company in rejuvenation and improvement of facial sagging symptoms

Design

It is a phase II interventional before-after clinical study. 21 healthy adult volunteers will participate in the study after signing informed consent. The study is not randomized.

Settings and conduct

The study will be conducted in Center for Research & Training in Skin Diseases and Leprosy from Tehran University of Medical Sciences. Participants will treat on full face by "facial microknife" and "microhook" of Ignite radio hybrid microknife device, made by Medaria company for one session.The assessments of Glogau criteria as well as skin biophysical parameters (skin elasticity, hydration, erythema, area and volume of nasolabial fold ,Skin thickness and density) will be performed before intervention, 4 and 8 weeks after treatment. The study is not blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: people aged between 30 to 60 years, People with facial skin wrinkles grade 2 and 3 based on Glogau scale and mild to moderate sagging (1 and 2) based on the Modified Fitzpatrick wrinkle criteria, Signing the informed consent form Exclusion criteria: History of using any type of device filler, including silicone, fat, collagen, hyaluronic acid or artificial materials in the treatment area, History of any type of cosmetic surgery during the last 3 years at the treatment area

Intervention groups

Intervention group: One session of full face treatment by "facial microknife" and "microhook" of Ignite radio hybrid microknife device, made by Medaria company. Intervention will be as a complete pass by a facial microknife on the entire face, and a pass with a microhook will be performed on the nasolabial folds.

Main outcome variables

Facial skin wrinkle grading, using Glogau scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210130050179N4**
Registration date: **2022-09-18, 1401/06/27**
Registration timing: **prospective**

Last update: **2022-09-18, 1401/06/27**
Update count: **0**

Registration date

2022-09-18, 1401/06/27

Registrant information

Name

Taraneh Yazdanparast

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8897 2220

Email address

drtaraneh@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-23, 1401/07/01

Expected recruitment end date

2023-03-21, 1402/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Safety and efficacy evaluation of "facial microknife" and "microhook" of Ignite radio hybrid microknife device, made by Medaria company in rejuvenation and improvement of facial sagging symptoms

Public title

Safety and efficacy evaluation of Ignite microknife device, made by Medaria company in rejuvenation and improvement of facial sagging symptoms

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

People aged between 30 to 60 years People with facial skin wrinkles grade 2 and 3 based on Glogau scale and mild to moderate sagging (1 and 2) based on the Modified Fitzpatrick Wrinkle Criteria Signing the informed consent form

Exclusion criteria:

History of using any type of device filler, including silicone, fat, collagen, hyaluronic acid or artificial materials in the treatment area History of any type of cosmetic surgery during the last 3 years at the treatment area Use of Isotretinoin in the last 6 months Suffering from collagen vascular diseases, diabetes, severe heart diseases History of treatment by Radio Frequency (RF) during the last year

Age

From **30 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **21**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee in research of medical school-Tehran University of Medical Sciences

Street address

Research and Technology Dept, 6th floor, Central Organization of the University, Ghods St., Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2022-08-30, 1401/06/08

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1401.415

Health conditions studied

1

Description of health condition studied

Skin aging

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

facial skin wrinkle grading, using Glogau scale

Timepoint

Before intervention, 4 and 8 weeks after treatment

Method of measurement

One independent dermatologist will perform clinical assessments using patients' photographs according to the Glogau scale.

2

Description

Facial skin sagging based on Modified Fitzpatrick Wrinkle Criteria

Timepoint

Before intervention, 4 and 8 weeks after treatment

Method of measurement

One independent dermatologist will perform clinical assessments using patients' photographs according to the Modified Fitzpatrick wrinkle scale.

Secondary outcomes

1

Description
Area and volume of nasolabial fold
Timepoint
Before intervention, 4 and 8 weeks after treatment
Method of measurement
VisioFace device

2

Description
Skin thickness and density
Timepoint
Before intervention, 4 and 8 weeks after treatment
Method of measurement
Skin ultrasound

Intervention groups

1

Description
Intervention group: One session of full face treatment by "facial microknife" and "microhook" of Ignite radio hybrid microknife device, made by Medaria company. Microknife intervention is a complete pass with a facial microknife on the entire face (Its surface is 15 x 15 mm and it has 35 needles with a penetration depth of 2.5 to 3 mm) and a pass with a microhook is performed on the nasolabial folds (The needles are like hooks and are locked when entering the skin).
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Center for research and training in skin diseases and leprosy
Full name of responsible person
Taraneh Yazdanparast
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No. 415, Shahid Naderi (Soheil) Street, Taleqani Avenue
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Maya Slim Ariya Company
Full name of responsible person
Mostafa Farahi
Street address
No. 216, Dastgerdi Avenue, Bokhara Street.
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918643471
Phone
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Email
externalaffairs@medariaco.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Maya Slim Ariya Company
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Taraneh Yazdanparast
Position
Research Physician
Latest degree
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Other areas of specialty/work
Dermatology
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Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Alireza Firooz

Position
Professor of dermatology

Latest degree
Specialist

Other areas of specialty/work
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Person responsible for updating data

Contact

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Research Expert

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Not applicable

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable