

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 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

Street address

No. 415, Shahid Naderi (Soheil) Street, Taleqani Avenue

City

Tehran

Province

Tehran

Postal code

1416613675

Phone

+98 21 8897 2220

Email

drtaraneh@yahoo.com

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.

City

Tehran

Province

Tehran

Postal code

918643471

Phone

+98 21 2222 2660

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

Ph.D.

Other areas of specialty/work

Dermatology

Street address

No. 415, Shahid Naderi (Soheil) Street, Taleqani Avenue

City

Tehran

Province

Tehran

Postal code

1416613675

Phone

+98 21 8896 0880

Email

drtaraneh@yahoo.com

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

Dermatology

Street address

No. 415, Shahid Naderi (Soheil) Street, Taleqani Avenue

City

Tehran

Province

Tehran

Postal code

1416613675

Phone

+98 21 8897 7921

Email

firozali@sina.tums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Maryam Ahmadi

Position

Research Expert

Latest degree

Master

Other areas of specialty/work

Clinical Research

Street address

No. 415, Shahid Naderi (Soheil) Street, Taleqani Avenue

City

Tehran

Province

Tehran

Postal code

1416613675

Phone

+98 21 8897 0658

Email

ahmadi.maryam648@gmail.com

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