

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Evaluation of the efficiency and safety of the RF Fractional microneedling system of Beaty skin device made by Faragard Fanavari Company in rejuvenating and improving the signs of aging facial skin

Protocol summary

Study aim

Evaluation of the efficiency and safety of the RF Fractional microneedling system using Beauty skin device made by Faragard Fanavari Company in rejuvenating and improving the signs of facial skin aging

Design

Single group, phase 2, before -after clinical study on 20 participants.

Settings and conduct

The study will be performed in Center for Research and Study in skin Diseases and Leprosy. 20 healthy volunteers will be selected and enrolled in the study after signing consent form. Two treatment sessions will be performed using Beaty skin device made by Fanavari faragard Company. Each session will be taken 45 minuets. Skin photography and measurement of skin biophysical parameters (including skin elasticity, area and volume of wrinkles as well as ultrasound parameters) will be performed before treatment, as well as 1 and 8 weeks later.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Mild to moderate wrinkles or sagging facial skin based on Glogau scale, Signing the consent form
Exclusion criteria: History of using any silicone, fat, collagen, hyaluronic acid or synthetic materials implant on face, History of RF treatment during the past year, History of Botox injection in face within the past 6 months, using Isotretinoin in the last 6 months, Active smoker in last 2 years, pregnancy or lactating

Intervention groups

2 sessions treatment with RF Fractional microneedling probe of Beauty skin device

Main outcome variables

Changing in facial skin wrinkles, using Glogau scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190210042676N11**

Registration date: **2020-11-18, 1399/08/28**

Registration timing: **retrospective**

Last update: **2020-11-18, 1399/08/28**

Update count: **0**

Registration date

2020-11-18, 1399/08/28

Registrant information

Name

Aniseh Samadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8897 2220

Email address

a_samadi@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-21, 1399/03/01

Expected recruitment end date

2020-08-22, 1399/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the efficiency and safety of the RF Fractional microneedling system of Beaty skin device made by Faragard Fanavari Company in rejuvenating and improving the signs of aging facial skin

Public title

Anti aging efficacy of radiofrequency system of Beaty skin device

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

mild to moderate wrinkles or sagging facial skin based on Glogau scale Signing the consent form for participation in the study

Exclusion criteria:

History of any implant placement including silicone, fat, collagen, hyaluronic acid or synthetic materials on face History of using RF during the past year History of Botox injection in face within the past 6 months Isotretinoin use in the last 6 months Active smoker in last 2 years Pregnancy or lactating

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: **20**

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 of 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

2019-12-31, 1398/10/10

Ethics committee reference number

IR.TUMS.VCR.REC.1398.762

Health conditions studied

1

Description of health condition studied

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Facial skin wrinkle grading, using Glogau scale

Timepoint

Before intervention and 1 and 8 weeks after last treatment session

Method of measurement

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

2

Description

Skin elasticity

Timepoint

Before intervention and 1 and 8 weeks after last treatment session

Method of measurement

Cutometry

Secondary outcomes

1

Description

Skin thickness and density

Timepoint

Before intervention and 1 and 8 weeks after last treatment session

Method of measurement

Skin ultrasound

2

Description

Area and volume of nasolabial fold

Timepoint

Before intervention and 1 and 8 weeks after last treatment session

Method of measurement

VisioFace camera

Intervention groups

1

Description

Intervention group: 2 sessions of full face treatment with RF Fractional microneedling probe of Beauty skin device. intensity 7 out of 10, active puls count 200 --250, depth 1 mm and time interval 1.5 second

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

Aniseh Samadi

Street address

No. 415, Shahid Naderi (Soheil) St., Taleqani Ave.

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1416613675

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+98 21 8897 0658

Email

dermalab@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Fanavari Faragard Company

Full name of responsible person

Payamreza Dabbagh

Street address

Khorasan Science and Technology Park, on 12 km of Asiaii road

City

Mashhad

Province

Razavi Khorasan

Postal code

9185173911

Phone

+98 51 3224 0054

Email

fanavari.tech@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Fanavari Faragard 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

Aniseh Samadi

Position

Clinical Lab Manager

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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aniseh_samadi@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

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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
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Province
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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