

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Investigating the safety and efficacy of fractional microneedle Sophia device, manufactured by Parnian Gostar Radiometer Company, in rejuvenating facial skin

Protocol summary

Study aim

Investigating the safety and efficacy of fractional microneedle Sophia device, manufactured by Parnian Gostar Radiometer Company, in rejuvenating facial skin

Design

Single group, phase 2, before -after clinical study on 21 participants.

Settings and conduct

The study will be performed in Center for Research and Study in skin Diseases and Leprosy. 21 healthy volunteers will be selected and enrolled in the study after signing consent form. Four treatment sessions will be performed using fractional microneedle Sophia device, manufactured by Parnian Gostar Radiometer Company. 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 4 and 8 weeks later.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Ages 30 to 60, 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 consent form for participation in the study 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

Intervention groups

4 sessions of full face treatment with fractional microneedle Sophia device, manufactured by Parnian Gostar Radiometer Company as a complete pass on full face. The diameter of the needles in this system is equal to 120µm.

Main outcome variables

Facial skin wrinkle grading, using Glogau scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190210042676N26**

Registration date: **2022-10-03, 1401/07/11**

Registration timing: **prospective**

Last update: **2022-10-03, 1401/07/11**

Update count: **0**

Registration date

2022-10-03, 1401/07/11

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

2022-10-23, 1401/08/01

Expected recruitment end date

2023-04-21, 1402/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the safety and efficacy of fractional microneedle Sophia device, manufactured by Parnian Gostar Radiometer Company, in rejuvenating facial skin

Public title

Investigating the safety and efficacy of fractional microneedle Sophia device, in rejuvenating facial skin

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Ages 30 to 60 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 consent form for participation in the study

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

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 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

2022-09-10, 1401/06/19

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1401.431

Health conditions studied**1****Description of health condition studied**

Skin ageing

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 last treatment session

Method of measurement

An independent dermatologist perform evaluation and scoring with the help of full face photos based on the percentage of improvement in facial wrinkles, using scale 1 to 4 (1 = no wrinkle 2 = Wrinkles in motion 3 = Wrinkles at rest 4 = Only wrinkles) .

Secondary outcomes**1****Description**

Skin thickness and density

Timepoint

Before intervention, 4 and 8 weeks after last treatment session

Method of measurement

Skin ultrasound

2**Description**

Area and volume of nasolabial fold

Timepoint

Before intervention, 4 and 8 weeks after last treatment session

Method of measurement

VisioFace camera

Intervention groups

1

Description

Intervention group: 4 sessions of full face treatment with fractional microneedle Sophia device, manufactured by Parnian Gostar Radiometer Company as a complete pass on full face. The diameter of the needles in this system is equal to 120µm.

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) Street, Taleqani Avenue

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Tehran

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1416613675

Phone

+98 21 8897 0658

Email

dermalab@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Parnian Gostar Radiometer Company

Full name of responsible person

Mahdi Zamanian

Street address

Unit 100, Aseman Vanak Official Tower, Vanak St.

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Postal code

1991945343

Phone

+98 21 8887 3479

Email

info@parniangostar.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Parnian Gostar Radiometer 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

Ph.D.

Other areas of specialty/work

Dermatology

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

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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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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