

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

To evaluate the safety and efficacy of High-Intensity Focused Ultrasound (HIFU) of Anika brand in skin rejuvenation

Protocol summary

Study aim

To evaluate the safety and efficacy of High-Intensity Focused Ultrasound (HIFU) (Anika device) in skin rejuvenation

Design

Single group, phase 2, before -after clinical study.
sample size is 30.

Settings and conduct

The study will be performed in Center for the Study and Research of Diseases of the Skin and Leprosy. 30 healthy volunteers will be selected and enrolled in the study after signing consent form. Treatment will be done using Anika HIFU device in a session for 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 3 and 6 months later.

Participants/Inclusion and exclusion criteria

General healthy women or men aged 30 to 60 who tend to do facial anti ageing and signed the consent form for participation in the study

Intervention groups

Intervention group: One 45 minute treatment session on lower face , using Cartridges 3 and 4.5 mm of Anika HIFU device

Main outcome variables

changing in facial skin wrinkle using global aesthetic improvement scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190210042676N5**

Registration date: **2020-03-11, 1398/12/21**

Registration timing: **retrospective**

Last update: **2020-03-11, 1398/12/21**

Update count: **0**

Registration date

2020-03-11, 1398/12/21

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

2019-05-22, 1398/03/01

Expected recruitment end date

2019-11-22, 1398/09/01

Actual recruitment start date

2019-05-22, 1398/03/01

Actual recruitment end date

2020-01-13, 1398/10/23

Trial completion date

2020-03-20, 1399/01/01

Scientific title

To evaluate the safety and efficacy of High-Intensity Focused Ultrasound (HIFU) of Anika brand in skin rejuvenation

Public title

Anti aging efficacy of HIFU therapy using Anika device

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

General health People who tend to do facial rejuvenation
 Signing the consent form for participation in the study
Exclusion criteria:
 History of skin tightening procedure within the past year
 History of Botox injection in the lower face within the past 6 months
 Presence of any active systemic or topical skin diseases which may affected wound healing
 Presence of a metal stent or implant in the facial area
 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: **30**
 Actual sample size reached: **30**

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

2019-05-07, 1398/02/17

Ethics committee reference number

IR.TUMS.VCR.REC.1398.115

Health conditions studied

1

Description of health condition studied

Skin ageing

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Changing in facial skin wrinkle using global aesthetic improvement scale

Timepoint

3 and 6 months after intervention

Method of measurement

One independent dermatologist will perform clinical assessments in a blinded fashion by scoring every photograph according to the global aesthetic improvement scale .

2

Description

Skin elasticity

Timepoint

before intervention and 3 and 6 months later

Method of measurement

Cutometry

Secondary outcomes

1

Description

Skin thickness and density

Timepoint

before intervention and 3 and 6 months later

Method of measurement

Skin ultrasound

2

Description

Area and volume of nasolabial fold

Timepoint

before intervention and 3 and 6 months later

Method of measurement

VisioFace

Intervention groups

1

Description

Intervention group: One treatment session in lower face, using Cartridges 3 and 4.5 of HIFU device (Anika)

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

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

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dermalab@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Parnian Gostar Parto Sanj company

Full name of responsible person

Naser Shahinfar

Street address

Unit100, First floor, Aseman Tower, Vanak st, Vanak sq

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1991945343

Phone

+98 21 8820 9274

Email

pgps.ir2017@gmail.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Parnian Gostar Parto Sanj 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**

Industry

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Aniseh Samadi

Position

Supervisor of clinical study unit

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

Aniseh Samadi

Position

Supervisor of clinical study unit

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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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

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

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