

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

Comparison of the effect of microneedling alone with microneedling combined with mesotherapy in the treatment of acne scars

Protocol summary

Study aim

Determining the effectiveness of microneedling alone compared to microneedling combined with mesotherapy in the treatment of acne scars

Design

Clinical trial, with parallel groups, single-blind, simple randomization, phase 4 is conducted on 20 patients referred to skin clinics of BooAli Hospital in Tehran in 2023

Settings and conduct

The study subjects will be selected from among the patients with acne scars referred to the skin clinics of Bo Ali Hospital in 2023 who meet the inclusion criteria so that the sample size reaches the desired number. Then the patients are divided into two simple random one-sided groups, which are matched with each other in terms of age and gender.

Participants/Inclusion and exclusion criteria

The conditions for entering the study include all patients aged 18 to 55 years with acne scars who have signed the informed consent form to participate in the study.

Exclusion criteria include: - pregnancy - Topical or oral retinoid use - Use of facial beauty skin methods including laser in the last 6 months - History of bleeding disorders - Simultaneous antithrombotic treatment - History of keloid scars - People with a history of drug sensitivity

Intervention groups

Intervention group one: In this group, patients are treated with microneedling alone. Intervention group two: In this group, patients are treated with microneedling and mesotherapy.

Main outcome variables

reducing hyperpigmentation; Reduction of hypertrophy or atrophy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230601058357N1**

Registration date: **2023-06-08, 1402/03/18**

Registration timing: **prospective**

Last update: **2023-06-08, 1402/03/18**

Update count: **0**

Registration date

2023-06-08, 1402/03/18

Registrant information

Name

Hengameh Sarnaz

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2200 6660

Email address

hengame.sarnaz@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-15, 1402/03/25

Expected recruitment end date

2023-09-16, 1402/06/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of microneedling alone with microneedling combined with mesotherapy in the treatment of acne scars

Public title

Investigating the effect of microneedling and mesotherapy in the treatment of acne scars

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 18 to 55 years Informed consent to participate in the study

Exclusion criteria:

pregnancy Topical or oral retinoid use Using facial beauty skin procedures including laser in the last 6 months History of bleeding disorders Concomitant antithrombotic treatment History of keloid scars Patients with a history of drug sensitivity

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

4

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

The table of random numbers is prepared and by placing a hand on a number randomly and moving the hand in one of the predetermined directions, each person is given a number. People who have even numbers in will be in intervention group A and individual numbers will be in the group Intervention B.

Blinding (investigator's opinion)

Single blinded

Blinding description

Participants in both groups remain unaware of the treatment method allocation during the study. The patient is informed that there are two types of treatment methods in a study and they will receive one of them randomly. Patients remain unaware of the name of the treatment method assigned to them.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Tehran Islamic Azad University Of Medical Sciences

Street address

Tehran Islamic Azad University of Medical Sciences, Khaghani St, Shariati Ave

City

Tehran

Province

Tehran

Postal code

19499160112

Approval date

2022-09-19, 1401/06/28

Ethics committee reference number

IR.IAU.TMU.REC.1401.224

Health conditions studied

1

Description of health condition studied

skin scar

ICD-10 code

L90.5

ICD-10 code description

Scar conditions and fibrosis of skin

2

Description of health condition studied

Acne

ICD-10 code

L70.9

ICD-10 code description

Acne, unspecified

Primary outcomes

1

Description

Determining the comparison of the effect of microneedling along with mesotherapy and microneedling alone on the treatment of acne scars

Timepoint

Three months after the intervention

Method of measurement

The opinion of two dermatologist separately

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients with acne scars are treated with microneedling along with mesotherapy

Category

Treatment - Other

2

Description

Intervention group: Patients with acne scars are treated by microneedling alone.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Booali hospital

Full name of responsible person

هدی قریشی راد

Street address

Booali Hospital, Damavand St., Imam Hossein Square

City

Tehran

Province

Tehran

Postal code

1711734365

Phone

+98 21 3334 8036

Fax

+98 21 3378 6182

Email

booali.hospital96@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

فرشاد هاشمیان

Street address

Tehran Islamic Azad University of Medical Sciences ,
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1916893813

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Email

chancellor@iautmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Islamic Azad University

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Hoda Ghoreshi Rad

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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Position

Associated professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There are currently no plans to publish.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available