Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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
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1711734365
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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 , Khaghani St, Shariati Ave
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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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Person responsible for updating data

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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