

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

Comparing the effect of microneedling by microneedling plus Triamcinolone solution in post operation scars

Protocol summary

Study aim

comparing the effect of microneedling by microneedling plus triamcinolone solution in post operation patients scar

Design

15 patients who underwent mammoplasty or abdominoplasty will be selected .6 to 8 weeks after surgery scar will be halved and in one half microneedling plus placebo and in the other half microneedling plus triamcinolone will be applied.

Settings and conduct

plastic ward of Imam Khomeini Hospital(Tehran) The scar of the patients will be treated 3 times by 1 month interval.in 3th and 6th month the scars will be evaluated.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: 15 patients who underwent surgery in department of plastic surgery of Tehran University.

Exclusion Criteria: Pregnancy .Herpes infection. immune deficiency. dermal infection history. Allergy to steroid or lidocaine-keloid treatment history.

Intervention groups

The patient scar will be halved. in one half microneedling plus triamcinolone solution and in other half microneedling plus placebo will be applied.

Main outcome variables

Vancouver scar scale(VSS)- VAS score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231222060490N1**

Registration date: **2024-02-10, 1402/11/21**

Registration timing: **retrospective**

Last update: **2024-02-10, 1402/11/21**

Update count: **0**

Registration date

2024-02-10, 1402/11/21

Registrant information

Name

Babak Hajipour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 914 477 3093

Email address

drhajipourb@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-03, 1402/09/12

Expected recruitment end date

2024-01-03, 1402/10/13

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of microneedling by microneedling plus Triamcinolone solution in post operation scars

Public title

Comparing the effect of microneedling by microneedling plus Triamcinolone solution in post operation scars

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Fifteen patients who underwent surgery in department of plastic surgery of Tehran University

Exclusion criteria:

Pregnancy active herpes infection- immune deficiency
dermal infections sensitivity to steroid and lidocaine-
history of keloid treatment in past 1 year

Age

No age limit

Gender

Female

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample size

Target sample size: **15**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description

For blinding, a placebo will be used and it will be provided to the person who performs microneedling, who does not know the content of the drug. The use of placebo and triamcinolone solution will be labeled A and B, and the person who performs microneedling will be on one side of microneedling with Solution A and on the other side, microneedling will be done with drug B.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tehran University of Medical Sciences-Imam Khomeini Hospital

Street address

Plastic surgery ward-11th flour-Mahdi clinic- Imam Khomeini Hospital-Keshavarz Boulevard.

City

Tehran

Province

Tehran

Postal code

۱۴۱۹۷۳۳۱۴۱

Approval date

2023-10-10, 1402/07/18

Ethics committee reference number**Health conditions studied****1****Description of health condition studied**

surgical scar

ICD-10 code

L90.5

ICD-10 code description

Scar conditions and fibrosis of skin

Primary outcomes**1****Description**

Vancouver Scar scale

Timepoint

3th and 6th month

Method of measurement

Scoring scars from 0 to 13 according to four vascular characteristics (zero: normal, one: pink, two: red, three: purple), height/thickness zero: smooth, one: < 2 mm, two: 2-5 mm, three: >5 mm, flexibility) pigmentation (zero: normal, one: hypopigmentation, two: hyperpigmentation), and flexibility (zero: normal, one: flexible, two: surrender, three: firm, four: rope, five: contraction).

2**Description**

patient satisfaction(VAS 100)

Timepoint

3th and 6th month

Method of measurement

VAS 100, which is scored by a millimeter scale. In this scale, patients are asked to place a vertical mark on the horizontal axis. mm line indicating their satisfaction with the treatment, where 0 indicates no satisfaction and 100 indicates extreme satisfaction.

Secondary outcomes

empty

Intervention groups**1****Description**

There is one group where the wound is divided into two parts and microneedling with triamcinolone solution will be done on one side.

Category

Treatment - Drugs

2**Description**

Control group: On the other side of the wound, microneedling will be done with a placebo solution. (Sterile distilled water will be used as a placebo). To the patient and the person performing the procedure, the drug and placebo will be introduced as drug number one and drug number two.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital- Plastic surgery ward

Full name of responsible person

Babak Hajipour

Street address

Plastic surgery ward-11th floor-Mahdi clinic- Imam Khomeini Hospital-Keshavarz Boulevard.Tehran

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+98 21 6118 0000

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drhajipourb@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Akbar sari

Street address

Deputy of research, 6th floor, Tehran university central office. Qods steet. Keshavarz Boulevard.

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+98 21 8163 3698

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vcr@sina.tums.ac.ir

Grant name

Grant code / Reference number

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

No

Title of funding source

there is no financial support from the 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

Tehran University of Medical Sciences

Full name of responsible person

Babak Hajipour

Position

fellow of plastic surgery

Latest degree

Specialist

Other areas of specialty/work

plastic surgery

Street address

Plastic surgery ward-11th floor-Mahdi clinic- Imam Khomeini Hospital-Keshavarz Boulevard

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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fellow

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Person responsible for updating data

Contact

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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

no additional information

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

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

Data Dictionary

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