

# 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 flour-Mahdi clinic- Imam Khomeini Hospital-Keshavarz Boulevard.Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

۱۴۱۹۷۳۳۱۴۱

**Phone**

+98 21 6118 0000

**Email**

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.

**City**

Tehran

**Province**

Tehran

**Postal code**

0000000000

**Phone**

+98 21 8163 3698

**Email**

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 flour-Mahdi clinic- Imam Khomeini Hospital-Keshavarz Boulevard

**City**

Tehran

**Province**

Tehran

**Postal code**

۱۴۱۹۷۳۳۱۴۱

**Phone**

+98 21 6119 0000

**Email**

drhajipourb@gmail.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Babak Hajipour

**Position**

fellow

**Latest degree**

Specialist

**Other areas of specialty/work**

plastic surgery

**Street address**

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

**City**

Tehran

**Province**

Tehran

**Postal code**

۱۴۱۹۷۳۳۱۴۱

**Phone**

+98 21 6119 0000

**Email**

drhajipourb@gmail.com

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Babak Hajipour

**Position**

fellow

**Latest degree**

Specialist

**Other areas of specialty/work**

plastic surgery

**Street address**

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

**City**

Tehran

**Province**

Tehran

**Postal code**

۱۴۱۹۷۳۳۱۴۱

**Phone**

+98 21 6119 0000

**Email**

drhajipourb@gmail.com

**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