

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jul 2026

### Investigating the efficacy of Subcision with and without carboxytherapy in the treatment of atrophic acne scars

#### Protocol summary

##### Study aim

Comparing the Effect of Subcision With and Without Carboxytherapy in the Treatment of Atrophic Acne Scars in Patients Referring to the Dermatology Clinic of Loghman-Hakim Hospital, Tehran in 2023

##### Design

This is a non-blinded randomized controlled clinical trial on 25 patients with atrophic acne scars. The intervention group receives treatment with Subcision and carboxytherapy, and the control group only receives Subcision. All patients receive both treatments on one side of the face and only receive Subcision on the other side. Random allocation software is used and the right and left sides of the face randomly receive one of these treatments. The results are compared after one and three months.

##### Settings and conduct

This study will be conducted in Loghman-e-Hakim Hospital. Patients are treated with Subcision. A tumescent solution is injected into the scar area and the subcutaneous fibrotic tissues are slowly separated by the blunt blade cannula. On one side of the face, 3 sessions of carboxytherapy are performed at intervals of 2 days.

##### Participants/Inclusion and exclusion criteria

All adult patients with rolling atrophic acne scars are included after written informed consent. Patients with active acne, active viral or bacterial infection, bleeding disorders, current use of systemic retinoid or during the preceding 12 months, hypertrophic scars, and hypersensitivity to anesthetic drugs are excluded.

##### Intervention groups

Twenty-five eligible patients are selected and divided into two groups, the right and left side of the face. One side of the face is randomly treated with carboxytherapy and Subcision and the other side only with Subcision. These two groups are compared with each other after one and three months after the treatment.

##### Main outcome variables

Changes in scar appearance one and three months after

the treatment

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230725058916N1**

Registration date: **2023-08-01, 1402/05/10**

Registration timing: **prospective**

Last update: **2023-08-01, 1402/05/10**

Update count: **0**

##### Registration date

2023-08-01, 1402/05/10

##### Registrant information

##### Name

Sina Mokhtari

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 81 3824 2668

##### Email address

sinamokhtari1996@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-09-06, 1402/06/15

##### Expected recruitment end date

2024-09-05, 1403/06/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Investigating the efficacy of Subcision with and without carboxytherapy in the treatment of atrophic acne scars

### Public title

Examining the benefits of combination treatment in acne

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Adult patients with atrophic rolling acne scars

#### Exclusion criteria:

Active acne Active bacterial or viral infections Bleeding disorders Current use of systemic retinoids or during the last year Hypertrophic scars Hypersensitivity to anesthesia drugs

### Age

From 18 years old

### Gender

Both

### Phase

N/A

### Groups that have been masked

No information

### Sample size

Target sample size: 25

### Randomization (investigator's opinion)

Randomized

### Randomization description

Random allocation software is used to allocate the treatment groups into two groups of Subcision alone and Subcision and carboxytherapy

### Blinding (investigator's opinion)

Not blinded

### Blinding description

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Research Ethics Committee of Skin Research Center-Shahid Beheshti University of Medical Sciences

##### Street address

Skin Research Center, Mino Dead end Alley, Shahr-dari St., Tehran, Iran

##### City

Tehran

##### Province

Tehran

### Postal code

1985717443

### Approval date

2023-03-12, 1401/12/21

### Ethics committee reference number

IR.SBMU.SRC.REC.1401.019

## Health conditions studied

### 1

#### Description of health condition studied

Atrophic acne scars

#### ICD-10 code

L70.0

#### ICD-10 code description

Acne vulgaris

## Primary outcomes

### 1

#### Description

Atrophic scar improvement

#### Timepoint

One and three months after treatment

#### Method of measurement

Comparison of photos before and after treatment, comments of the patient and the attending physicians (2 physicians) (Goodman and Baron's acne scar grading system)

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Patients receive both Subcision and carboxytherapy on one side of the face. First, a tumescent solution is injected into the acne scar area. Fibrotic tissues are slowly separated by the blunt blade cannula. Finally, the cannula entry area is bandaged. Three sessions of carboxytherapy are performed with a pressure of 275-320, and a volume of 50-70 cc of gas is injected using an insulin needle.

#### Category

Treatment - Other

### 2

#### Description

Control group: Patients only receive Subcision on the other side of the face

#### Category

Treatment - Other

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Tehran Loghman-e-Hakim Hospital

**Full name of responsible person**

Dr Sina Mokhtari

**Street address**

Loghman-e-Hakim Hospital, Makhsoos St., Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1333635445

**Phone**

+98 21 5102 5000

**Email**

loghmanlibrary@sbmu.ac.ir

**Web page address**

<https://lhmc.sbmu.ac.ir/>

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Dr Afshin Zarghi

**Street address**

Next to Taleghani Hospital, Shahid Abbass Arabi St., Chamran Expressway, Tehran, Iran

**City**

Tehran

**Province**

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**Postal code**

1985717443

**Phone**

+98 21 2243 9780

**Email**

info@sbmu.ac.ir

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

Yes

**Title of funding source**

Shahid Beheshti University of Medical Sciences

**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**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Mahdi Gheysari

**Position**

Associate Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dermatology

**Street address**

Loghman-e-Hakim Hospital, Makhsoos St., Tehran, Iran

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Dr.mehdigheisari@gmail.com

## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Mahdi Gheysari

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dermatology

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Dr.mehdigheisari@gmail.com

**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Sina Mokhtari

**Position**

Dermatology resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dermatology

**Street address**

Loghman-e-Hakim St., Makhsoos Hospital, Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1333635445

**Phone**

+98 21 5102 5000

**Email**

sinamokhtari1996@yahoo.com

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is 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**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

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

**Title and more details about the data/document**

The anonymous dataset is available for sharing with researchers upon a reasonable request. The study protocol, analysis, and results will be published in the form of research articles.

**When the data will become available and for how long**

The dataset is accessible 6 months after the results are published

**To whom data/document is available**

All researchers upon a reasonable request

**Under which criteria data/document could be used**

Systematic review and meta-analysis, for the researcher's own knowledge

**From where data/document is obtainable**

Corresponding author's email or the information mentioned for the person corresponding to update the state of the clinical trial

**What processes are involved for a request to access data/document**

After receiving the request, a decision is made after consulting with the research members and the decision to provide the data file to the researcher is announced to her/him.

**Comments**