

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 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

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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

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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

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Person responsible for scientific inquiries

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Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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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

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Province

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Postal code

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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