

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Evaluation of the efficacy of SVF cells on the effect of subcision method in the treatment of acne scars; A double blind clinical trial

Protocol summary

Study aim

Achievement of combination treatment with higher efficacy and lower side effects than previous treatment methods of acne scars.

Design

Phase 3 controlled randomized double-blind clinical trial with parallel groups design of 10 patients. For randomization, Simple randomization by coin tossing was used.

Settings and conduct

Ten patients with acne scars were entered to study. In these patients, subcision technique was randomly performed on one side of the face and subcision technique plus SVF on the opposite side of the face. The degree of neocollagenesis was evaluated by ultrasound before and 3 months after intervention. Recovery rate was assessed using a patient-based mental scoring system and visual evaluation of scars.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age range of 20-50 years; Moderate and severe scars; Conscious consent for participation in the study Exclusion criteria: Pregnancy and lactation; Malignancy

Intervention groups

Control: subcision technique on one side of the face
Case: subcision technique plus SVF on the opposite side of the face

Main outcome variables

Scar size; Neocollagenesis; Patient mental scoring; Physician scoring

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211121053126N1**

Registration date: **2022-01-04, 1400/10/14**

Registration timing: **registered_while_recruiting**

Last update: **2022-01-04, 1400/10/14**

Update count: **0**

Registration date

2022-01-04, 1400/10/14

Registrant information

Name

Azadeh Seifadini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8670 5503

Email address

dr.az.seifadini@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-26, 1400/10/05

Expected recruitment end date

2022-02-09, 1400/11/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the efficacy of SVF cells on the effect of subcision method in the treatment of acne scars; A double blind clinical trial

Public title

Effect of Svf and Subcision in Acne Scar

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 20-50 years Moderate and severe acne scars No treatment in 3months ago Conscious consent to participate in the study

Exclusion criteria:

Pregnancy and lactation Malnancy

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **10**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization and coin tossing methods were used. Performance of alone subcision method was considered as heads and combination therapy was considered as tails and random assignment was performed by tossing a coin.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants as to which side of the face the Svf injection was given. A dermatologist who evaluates the outcome.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

NO.9, Bloc 446, Shirdam Town, Babaei Highway

City

Tehran

Province

Tehran

Postal code

1234567890

Approval date

2021-11-26, 1400/09/05

Ethics committee reference number

IR.IUMS.FMD.REC.1399.410

Health conditions studied

1

Description of health condition studied

Acne Scars

ICD-10 code

L70.8

ICD-10 code description

Other acne

Primary outcomes

1

Description

scar mental score

Timepoint

Before and 3 months after the intervention

Method of measurement

Patient Mental Scoring System, Patients are asked to rate the severity of scars seen on their face based on a 0 to 10 scoring comparison (0 without scars and 10 severe scars).

2

Description

scar size

Timepoint

Before and 3 months after the intervention

Method of measurement

Photography with visioface device

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: subcision technique plus SVF

Category

Treatment - Drugs

2

Description

Control group: subcision technique

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasool Akram Hospital

Full name of responsible person

Masoumeh Roohaninasab

Street address

Hazrat Rasoul Akram Hospital, Niayesh Ave.,
Sattarkhan Street, Tehran. Iran

City

Tehran

Province

Tehran

Postal code

۱۴۵۶۱۳۱۳۱

Phone

+98 21 6435 1000

Email

rohaninasabm@iums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Najmosadat Atefi

Street address

Iran University of Medical Sciences, next to Milad
Tower, Hemmat Highway, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Phone

+98 21 8670 2213

Email

najmosadatatefi8931@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Azadeh Seiphaddini

Position

Dermatology student

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

Street address

Iran University of Medical Sciences, next to Milad
Tower, Hemmat Highway, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Phone

+98 21 8670 2213

Email

dr.az.seifadini@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Masoumeh Roohaninasab

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

Street address

Iran University of Medical Sciences, next to Milad
Tower, Hemmat Highway, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Phone

+98 21 8670 2213

Email

rohaninasab@iums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Masoumeh Roohaninasab

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

Street address

Iran University of Medical Sciences, next to Milad Tower, Hemmat Highway, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Phone

+98 21 8670 2213

Email

rohaninasabm@iums.ac.ir

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

Yes - There is a plan to make this available

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

No - There is not 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

Title and more details about the data/document

Data on the main outcome of the study (Oscar recovery rate) will be published in the final report and article.

When the data will become available and for how long

The data will be available one month after the final report.

To whom data/document is available

The data will be available to academic researchers.

Under which criteria data/document could be used

Researchers who intend to meta-analyze About the subject or to define a similar study in a different statistical population can access the data.

From where data/document is obtainable

Azadeh Seifadini: dr.az.seifadini@gmail.com

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

After sending the request via email, the data will be provided to the applicant in less than a month.

Comments