Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 neoclagenosis 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; Neoclagenosis; 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
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Name of organization / entity

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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 Malignancy

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

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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
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Hazrat Rasoul Akram Hospital, Niayesh Ave., Sattarkhan Street, Tehran. Iran
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Sponsors / Funding sources

1

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Name of organization / entity
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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
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
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Dermatology student
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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