

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Oct 2023

### Evaluation of the effectiveness of stromal vascular fraction cells in the impact of Nanofat on acne scar

#### Protocol summary

##### Study aim

Evaluation of the impact of SVF cells in the effectiveness of Nanofat on acne scar healing

##### Design

This study will be a randomized single-blind clinical trial on 10 patients. Target population is patients with facial acne scars who referred to a dermatology clinic in 1399.

##### Settings and conduct

In these patients, after preparing SVF and Nanofat by taking 100 ccs of fat from the thigh area, the scars on one side of the face are treated with Nanofat, which is, in fact, the control group, and the scars on the other side are treated with Nanofat and SVF together, which is the intervention group. Post-treatment evaluation of patients three months after the intervention is performed as follows: 1)Evaluation of the change in scar size based on the digital re-imaging 2)Evaluating the extent of Neoclagenesis by ultrasound.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: being infected with two to three-grade acne scars Fits Patrick type IV to V Exclusion criteria: Age under 18 years old, being under treatment with anticoagulants or steroids, active skin or systemic infection, malignancy or history of chemotherapy, breastfeeding or pregnancy, history of receiving any analgesic drugs in the last week before the intervention.

##### Intervention groups

In patients with acne scars, after preparing SVF and Nanofat by taking 100 ccs of fat from the thigh area, the scars on one side of the face are treated with Nanofat, which is, in fact, the control group, and the scars on the other side are treated with Nanofat and SVF together, which is the intervention group.

##### Main outcome variables

Neoclagenesis, size of the acne scar and scar grade changes

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200901048586N1**

Registration date: **2021-12-09, 1400/09/18**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-12-09, 1400/09/18**

Update count: **0**

##### Registration date

2021-12-09, 1400/09/18

##### Registrant information

##### Name

Sepideh Moradi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2285 2343

##### Email address

sepideh.moradi1989@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-11-22, 1400/09/01

##### Expected recruitment end date

2021-12-22, 1400/10/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of the effectiveness of stromal vascular fraction cells in the impact of Nanofat on acne scar

#### Public title

Evaluation of the impact of adipose tissue stem cells on the effectiveness of fat particles injection, prepared from patient's adipose tissue, in the treatment of Acne scars

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

The patient has the informed consent to participate in the study. The patient should be able to participate regularly at all appointments and follow-up sessions. The patient should not have any serious internal disease. The patient should not have accompanying disease on the treatment site.

##### Exclusion criteria:

Taking anticoagulants and steroids Existence of active skin or systemic infection Having a malignancy or a history of receiving chemotherapy medications Breastfeeding or pregnancy History of receiving any analgesic medications during the week before of the intervention

#### Age

From **18 years** old to **50 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

- Participant

#### Sample size

Target sample size: **10**

More than 1 sample in each individual

Number of samples in each individual: **2**

Injection of Nanofat on one side of the face and injection of Nanoft and SVF on the other side of the face

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Randomly blinded clinical trial Nanofat cells are injected into scars on both sides of the face and SVF cells are injected randomly into scars on only one side of the face.

#### Blinding (investigator's opinion)

Single blinded

#### Blinding description

In this study, acne scars on both sides of the face are treated with Nanofat injection. However, SVF injections are performed randomly on only one side, and the patient does not know which side the SVF injection is in.

#### Placebo

Not used

#### Assignment

Single

#### 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

Iran University of Medical Sciences, Tehran, Iran

##### City

Tehran

##### Province

Tehran

##### Postal code

1449614535

#### Approval date

2020-07-28, 1399/05/07

#### Ethics committee reference number

IR.IUMS.FMD.REC.1399.291

### 2

#### Ethics committee

##### Name of ethics committee

Ethics committee of Iran university of Medical Sciences

##### Street address

Iran University of Medical Sciences, Tehran, Iran

##### City

Tehran

##### Province

Tehran

##### Postal code

1449614535

#### Approval date

2020-09-26, 1399/07/05

#### Ethics committee reference number

IR.IUMS.FMD.REC.1399.291

## Health conditions studied

### 1

#### Description of health condition studied

Acne scar

#### ICD-10 code

L70

#### ICD-10 code description

Acne

### 2

#### Description of health condition studied

Acne scar

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

## 1

### Description

In all patients, the initial grade of acne scar is qualitatively determined based on the Goodman and Baron grading system (grade 1 grade 2 grade 3 grade 4).

### Timepoint

Acne scar Examination before the intervention is one month and then three months later.

### Method of measurement

1) Scar size change evaluation based on digital re-imaging, 2)Evaluating the extent of Neoclagenesis by ultrasound.

## Secondary outcomes

empty

## Intervention groups

## 1

### Description

Control group: In these patients, after preparing SVF and Nanofat by taking 100 ccs fat from the thigh area, the scars on one side of the face are treated with only Nanofat. However, the scars on the other side are treated with Nanofat and SVF both together. The part of the face that was treated with Nanofat alone is the control group

### Category

Treatment - Other

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Rasul akram hospital

#### Full name of responsible person

Sepideh Moradi

#### Street address

Sattar Khan St., Maziar Mansouri St., Rasoul Akram Hospital

#### City

Tehran

#### Province

Tehran

#### Postal code

1445613131

#### Phone

+98 21 6655 9595

#### Email

sepideh.moradi1989@gmail.com

## Sponsors / Funding sources

## 1

### Sponsor

Name of organization / entity

Iran University of Medical Sciences

### Full name of responsible person

Dermatology and Stem Cell Research Center of Tehran University of Medical Sciences

### Street address

Tehran, Dermatology and Stem Cell Research Center, No .4,Maryam Dead End,South Kamaranieh (Pashazhari) Ave

### City

Tehran

### Province

Tehran

### Postal code

1417653761

### Phone

+98 21 2665 7541

### Email

info@skinstemcell.ir

### 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

Sepideh Moradi

#### Position

Resident

#### Latest degree

Medical doctor

#### Other areas of specialty/work

Dermatology

#### Street address

No. 2, Unit 3, Shahid Jafari Alley, 3rd Dashtestan St., Pasdaran St.

#### City

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#### Postal code

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#### Email

sepideh.moradi1989@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Sepideh moradi

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dermatology

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Sepideh Moradi

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

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## Sharing plan

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

Undecided - It is not yet known if there will be 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**

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