

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 Nanoft by taking 100 ccs fat from the thigh area, the scars on one side of the face are treated with only Nanoft. However, the scars on the other side are treated with Nanoft and SVF both together. The part of the face that was treated with Nanoft 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

Tehran

Province

Tehran

Postal code

1947948584

Phone

+98 21 2284 1683

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

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Person responsible for updating data

Contact

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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