

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

Comparison of the effectiveness of adipose-derived stem cell conditioned medium (ADSC_CM) combined with microneedling or fractional carbon dioxide laser on acne scar healing

Protocol summary

Study aim

Evaluation the effect of conditioned medium of adipose derived stem cells on healing of scar after fractional Carbon Dioxide(CO₂) laser resurfacing or micro needling

Design

The aim of this study was to evaluate the efficacy and side effects of using CO₂ laser with conditioned medium in comparison with microneedling with conditioned medium in 30 patients with acne scars who were enrolled in block randomized method. In each session immediately after laser treatment, one side of the patient's face (intervention group) conditioned media of adipose derived stem cells, and the other side of the face (control group) physiological serum is applied topically on the laser site for one hour. This procedure is repeated 4 times with 4 week intervals.

Settings and conduct

This design is done at the skin and stem cell research center of Tehran university of medical sciences and without the patient's knowledge, after the CO₂ laser or microneedling, one side of the face of conditioned media of ADSC and other side for blinding is used of the physiology serum in the scars.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 20-60; Developing middle to severe atrophic scars in face region. Exclusion criteria: Pregnancy and breastfeeding; Active infection in face; Using any local drugs on face except sun protection creams in last month

Intervention groups

Intervention group 1: The whole face is treated with CO₂ laser. Immediately, on one side of the face, the conditioned media of adipose derived stem cells, and on the other side of the face, physiological serum is applied topically to the scar site. Intervention group 2: The whole face is treated with microneedling. Then, similar to the

first intervention group, conditioned medium and physiological serum are used on both sides of the face.

Main outcome variables

scar's surface; side effects; patient's satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20080901001159N33**

Registration date: **2021-06-01, 1400/03/11**

Registration timing: **prospective**

Last update: **2021-06-01, 1400/03/11**

Update count: **0**

Registration date

2021-06-01, 1400/03/11

Registrant information

Name

Mohamad Ali Nilforoushzadeh

Name of organization / entity

Skin and Stem Cell Research Center, Tehran
University of Medical sciences

Country

Iran (Islamic Republic of)

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+98 21 2220 5158

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-22, 1400/04/01

Expected recruitment end date

2021-08-23, 1400/06/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effectiveness of adipose-derived stem cell condition medium (ADSC_CM) combined with microneedling or fractional carbon dioxide laser on acne scar healing

Public title
Evaluation the effect of conditioned media of adipose driven stem cells on acne scar

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 20-60 Having middle to severe atrophic scar in face region

Exclusion criteria:

Pregnancy and breastfeeding History of cancer
Pregnancy, breastfeeding Patients with active acne
Vascular / muscle collagenous disorders of immunodeficiency or use of immunosuppressive drugs
People with herpes disease are active People with Mental Disorders Active infection in the face

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

1

Groups that have been masked

- Participant

Sample size

Target sample size: **30**
More than 1 sample in each individual
Number of samples in each individual: **2**
A half face will be considered as the control group and one half as an intervention group

Randomization (investigator's opinion)

Randomized

Randomization description

In this method, block randomization is used. Each patient was considered as a block and left and right sides of their face were randomly assigned to two groups using cards with study groups written on them.

Blinding (investigator's opinion)

Single blinded

Blinding description

In each group, both sides of the face will be treated with CO2 laser or microneedling at the patient's scar area, immediately on one side of the face, the conditioned media of adipose derived stem cells and the other side of the face saline solution is used topically on the scar.

Placebo

Used

Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Keshavarz blvd

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2021-02-14, 1399/11/26

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1399.1131

Health conditions studied

1

Description of health condition studied

atrophic scar

ICD-10 code

L90.5

ICD-10 code description

Scar conditions and fibrosis of skin

Primary outcomes

1

Description

Scar size

Timepoint

before and 3month after the intervention

Method of measurement

visioface

2

Description

side effects

Timepoint

One week after session

Method of measurement

Questionnaire and visit

3

Description

Patient Satisfaction

Timepoint

Three and six months after the last treatment session

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: One side of the face after being anesthetized, is first treated with Fractional Laser Co2, and then adipose conditioned media of adipose derived stem cells is applied topically to the scars for one hour. This procedure is repeated 4 times with intervals of 4 weeks.

Category

Treatment - Other

2

Description

Intervention group: One side of the face after being anesthetized, is first treated with microneedling, and then adipose conditioned media of adipose derived stem cells is applied topically to the scars for one hour. This procedure is repeated 4 times with intervals of 4 weeks.

Category

Treatment - Other

3

Description

Control group: (Other side of face) After sufficient anesthesia, first treatment with Fractional Laser Co2, and then physiological serum is applied topically to the site of the scars for one hour. This procedure is repeated 4 times with intervals of 4 weeks.:

Category

Treatment - Other

4

Description

Control group: (Other side of face) After sufficient anesthesia, first treatment with microneedling, and then physiological serum is applied topically to the site of the scars for one hour. This procedure is repeated 4 times with intervals of 4 weeks.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinics of Skin and Stem cell Research Center of Tehran University of Medical Sciences

Full name of responsible person

Maryam nouri

Street address

No 4, Maryam Alley, South Kamraniyeh Street, Tehran, Iran

City

Tehran

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1937957511

Phone

+98 21 2221 5558

Email

m.nouri3023@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Abbas Ali Karimi

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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

Tehran 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

Skin and Stem cell Research Center of Tehran
University of Medical Sciences

Full name of responsible person

Maryam Nouri

Position

Researcher

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Skin and Stem cell Research Center of Tehran
University of Medical Sciences

Full name of responsible person

Mohammad Ali Nilforoushzadeh

Position

Professor

Latest degree

A Level or less

Other areas of specialty/work

Dermatology

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Mona mahmoubbeyk

Position

Researcher

Latest degree

Ph.D.

Other areas of specialty/work

Cell Developmental Biology

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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

Not applicable

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

Not applicable

Data Dictionary

Not applicable