

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Sep 2026

Evaluation and comparison of the effect of simultaneous injection of Stromal Vascular Fraction with fractional CO2 laser in the treatment of burn scar

Protocol summary

Study aim

Evaluation and comparison of the effect of simultaneous injection of Stromal Vascular Fraction with fractional CO2 laser in the treatment of burn scar

Design

This study is performed as a phase 1 clinical trial on 10 patients. After obtaining sufficient anesthesia, the patient's scar treatment areas are treated with fractional CO2 on both sides of the face. Immediately after the laser, one patient scar (intervention group) is injected with SVF, and the other scar (control group) is injected with physiological serum. All patients are photographed with a digital camera before treatment and at each visit. To determine the extent of improvement and compare the two sides, at the end of the study, photos of patients are examined by two neutral dermatologists. Patient satisfaction is also recorded and the results are compared.

Settings and conduct

This project is performed in the Skin and Stem Cell Research Center of Tehran University of Medical Sciences, and after the laser, one side of the SVF scar is injected and the other side is injected in the areas of the physiological serum scar.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with skin type 1-4, patients with atrophic burn scars in more than one organ from 5 years ago to 3 months ago. Exclusion criteria: Age under 18 years, patients who have received laser treatment in the last three months, patients with active colloidal scar or active skin lesion at the injection site, patients with coagulation and platelet disorders, patients with a history of anticoagulants.

Intervention groups

Patients with fractional CO2 laser with SVF will receive three sessions one month apart. In control group Patients will receive fractional CO2 laser and physiological saline

three sessions one month apart.

Main outcome variables

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

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200127046282N15**

Registration date: **2022-05-04, 1401/02/14**

Registration timing: **registered_while_recruiting**

Last update: **2022-05-04, 1401/02/14**

Update count: **0**

Registration date

2022-05-04, 1401/02/14

Registrant information

Name

Sona Zare

Name of organization / entity

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

Country

Iran (Islamic Republic of)

Phone

+98 21 2665 7438

Email address

sonazarebio@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-19, 1401/01/30

Expected recruitment end date

2022-08-21, 1401/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation and comparison of the effect of simultaneous injection of Stromal Vascular Fraction with fractional CO2 laser in the treatment of burn scar

Public title

Evaluation of the effect of simultaneous injection of SVF with fractional CO2 laser in the treatment of burn scar

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with skin type 1-4 Patients with atrophic burn scars in more than one organ from 5 years ago to 3 months ago

Exclusion criteria:

Age under 18 years Patients who have received laser treatment in the last three months Patients with active colloidal scar or active skin lesion at the injection site Patients with coagulation and platelet disorders Patients with a history of underlying disease such as diabetes and autoimmune connective tissue disease that affect wound healing Patients with active viral infections Patients with a history of anticoagulants History of malignancy or receiving chemotherapy Pregnancy and lactation

Age

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

Gender

Both

Phase

1

Groups that have been masked*No information***Sample size**Target sample size: **10****Randomization (investigator's opinion)**

Not randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description

The data analyzer will not be aware of the intervention groups (laser and SVF-laser and normal saline).

Therefore, the study will be performed blindly.

Placebo

Not 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

2021-11-10, 1400/08/19

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1400.921

Health conditions studied**1****Description of health condition studied**

burn scar

ICD-10 code

L90

ICD-10 code description

Atrophic disorders of skin

Primary outcomes**1****Description**

Scar size

Timepoint

before and 2 month after the intervention

Method of measurement

visioface

Secondary outcomes**1****Description**

Side effects

Timepoint

One week after treatment

Method of measurement

Questionnaire and visit

2**Description**

Patient Satisfaction

Timepoint

Two months after treatment

Method of measurement

Questionnaire

Intervention groups

1

Description

Patients with the deka fractional CO2 laser, along with 2 cc of SVF cells, will receive three sessions one month apart.

Category

Treatment - Other

2

Description

Control group: Patients will receive fractional CO2 laser and physiological saline three sessions one month apart.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

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

Full name of responsible person

Mohammad Ali Nilforoushzadeh

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No 4, Maryam Alley, South Kamraniyeh Street,
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Akbar Fotoohi

Street address

Central University Organization, sixth floor, Vice
Chancellor for Research and Technology, corner of
Quds Street, Keshavarz Boulevard

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vcr@tums.ac.ir

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, Tehran
University of Medical Sciences

Full name of responsible person

Sona Zare

Position

Researcher

Latest degree

Ph.D.

Other areas of specialty/work

Cellular and Molecular Biology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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

Full name of responsible person

Masoumeh Roohaninasab

Position

Assistant professor

Latest degree

Specialist

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

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

Person responsible for updating data**Contact****Name of organization / entity**

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

Full name of responsible person

Sona Zare

Position

Researcher

Latest degree

Ph.D.

Other areas of specialty/work

Cellular and Molecular Biology