

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jun 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

##### Street address

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

##### City

Tehran

##### Province

Tehran

##### Postal code

1937957511

##### Phone

+98 21 2665 7438

##### Email

Nilforoosh@sina.tums.ac.ir

## 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

##### City

Tehran

##### Province

Tehran

##### Postal code

1937957511

##### Phone

+98 21 8163 3698

##### Email

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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No 4, Maryam Alley, South Kamraniyeh Street, Tehran

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##### Province

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1937957511

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##### Email

sonazarebio@gmail.com

## 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**

Dermatology

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**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

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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