# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

13 Nov 2026

## Evaluation of the effectiveness and satisfaction of fractional carbon dioxide laser and stromal vascular fraction in comparison with laser alone in the treatment of burn scars

## Protocol summary

**Study aim**
Evaluation of the effectiveness and satisfaction of fractional co2 laser and stromal vascular fraction (SVF) in the treatment of burn scar

**Design**
The clinical trial, with parallel groups, double-blind, simple randomized by sealed envelopes, phase 2-3 on 10 patients

**Settings and conduct**
The intervention will be performed at the Skin and Stem Cell Research Center. In this study, 10 patients with burn scars will be selected. Patients will receive 3 sessions of fractional CO2 laser treatment with an interval of one month. At the end of the first and third sessions, the SVF will be injected into the selected scar as the treatment group and the physiological serum will be injected at the other scar as the control group. The patient, the outcome assessor, and the data analyst are unaware of the type of intervention performed on each burn scar.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: skin type 1-4, atrophic burn scars in more than one limb from five years ago to the last 3 months. Exclusion criteria: Age under 18 years, Laser treatment in the last three months, Active colloidal scar at the injection site, Coagulation and platelet disorders or a history of taking anticoagulants, Underlying diseases such as diabetes and autoimmune connective tissue disease that affect the wound healing process, Active viral infections, History of malignancy or receiving chemotherapy, Pregnancy, Lactation

**Intervention groups**
In each patient, three sessions of fractional carbon dioxide laser will be performed on each burn scar every one month. At the end of the first and third session, the stromal vascular fraction will be injected into one of the scars as the treatment group, another scar of the same patient will be injected the physiological serum as the control group.

**Main outcome variables**
The effectiveness of treatment, patient satisfaction, physician satisfaction

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20210515051307N1**
Registration date: **2021-11-14, 1400/08/23**
Registration timing: **registered_while_recruiting**

Last update: **2021-11-14, 1400/08/23**
Update count: **0**

**Registration date**
2021-11-14, 1400/08/23

**Registrant information**

**Name**
fariba khodadad

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2021-08-23, 1400/06/01

**Expected recruitment end date**
2022-03-20, 1400/12/29

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Evaluation of the effectiveness and satisfaction of fractional carbon dioxide laser and stromal vascular fraction in comparison with laser alone in the treatment of burn scars

**Public title**

Investigation of the effect of stromal vascular fraction on burn scars

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Patients with skin type 1-4 Patients with atrophic burn scars in more than one limb, from five years ago to the last 3 months

**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 or a history of taking anticoagulants. Patients with a history of underlying diseases such as diabetes and autoimmune connective tissue disease that affect the wound healing process Patients with active viral infections History of malignancy or receiving chemotherapy Pregnancy and lactation

**Age**

From **18 years** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

- Participant
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **10**

More than 1 sample in each individual

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

At the end of the first session of laser treatment, the stromal vascular fraction will be injected into a scar of the patient as the treatment group. In another scar of the same patient, the physiological serum will be injected as the control group.

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this study, 10 patients with inclusion and exclusion criteria are selected. In each patient by simple randomization method, one burn scar is selected as the intervention group and another scar of the same patient is selected as the control group. For each burn scar, one envelope is randomly selected from two sealed envelopes . The letter a or b is written on each envelope. Envelopes a belong to the intervention group and envelopes b belong to the control group. The patient does not know to which group each envelope is assigned.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In this study, the patient is unaware of the type of intervention performed on each burn scar.To blind the patient, a paper cover with the patient's name is attached on the body of the injection syringes .The outcome assessor is a dermatologist who has only images and biometric information of each scar for Vancouer scoring and he does not know the type of intervention.The data analyzer also is a statistician who has only the data to analyze and is not aware of the type of intervention.

**Placebo**

Used

**Assignment**

Parallel

**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, Shahid Hemmeat Highway

**City**

Tehran

**Province**

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**Postal code**

1449614535

**Approval date**

2021-05-08, 1400/02/18

**Ethics committee reference number**

IR.IUMS.FMD.REC.1400.099

### 2

**Ethics committee**

**Name of ethics committee**

Ethics Committee of Tehran University of Medical Sciences

**Street address**

Keshavarz Boulevard - Intersection of Ghods Street - Central Building of Tehran University of Medical Sciences

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**Province**

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**Postal code**
1417653761
**Approval date**
2021-11-12, 1400/08/21
**Ethics committee reference number**
IR.TUMS.MEDICINE.REC.1400.921

## Health conditions studied

### 1

**Description of health condition studied**
Burn scars
**ICD-10 code**
L90.5
**ICD-10 code description**
Scar conditions and fibrosis of skin

## Primary outcomes

### 1

**Description**
The effectiveness of treatment
**Timepoint**
Before starting the trial, before the second and third sessions of treatment with laser and two months after the last session
**Method of measurement**
Photography and biometry of the burn scars will be done. The scoring of the scars will be performed based on the Vancouver scoring system.

### 2

**Description**
Patient satisfaction from treatment
**Timepoint**
Two months after the last session of treatment with laser
**Method of measurement**
Patient global assessment score

### 3

**Description**
Physician satisfaction from treatment
**Timepoint**
Two months after the last session of treatment with laser
**Method of measurement**
Physician global assessment score

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Intervention group: Patients will receive three sessions of fractional carbon dioxide laser treatment at one-month intervals. Deka fractional carbon dioxide laser device will be used to perform the laser treatment. Its setting will be determined based on the thickness of the scar and the patient's skin type. At the end of the first and third sessions of laser treatment, the Stromal vascular fraction injection will be performed in one of the patients' scars. To prepare it, depending on the required amount and the doctor's diagnosis, between 120 and 200 ccs of fat is drawn from the patient's side or abdomen. Then, after centrifugation and processing, the stromal vascular fraction is isolated. It will be injected into the scar with an insulin syringe.
**Category**
Treatment - Other

### 2

**Description**
Control group: Patients will receive three sessions of fractional carbon dioxide laser treatment at one-month intervals. Deka fractional carbon dioxide laser device will be used to perform the laser treatment. Its setting will be determined based on the thickness of the scar and the patient's skin type. At the end of the first and third sessions of laser treatment, in another scar of the patient as the control group, 5cc of the physiological serum will be injected with an insulin syringe.
**Category**
Treatment - Other

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Hazrate Fatemeh Hospital
**Full name of responsible person**
Fariba Khodadad
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21st St, Jamaluddin Asadabadi St.
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## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Skin and Stem cell Research Center of Tehran University
**Full name of responsible person**
Dr. Mohammad Ali Nilforuzadeh

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info@skinstemcell.ir
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Skin and Stem cell Research Center of Tehran University
**Proportion provided by this source**
70
**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

**2**

**Sponsor**
**Name of organization / entity**
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**Phone**
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research_m@iums.ac.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**
30
**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**
Fariba Khodadad
**Position**
resident
**Latest degree**
Medical doctor
**Other areas of specialty/work**
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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Fariba Khodadad

**Position**
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**Latest degree**
Medical doctor

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Dermatology

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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