

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 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 Vancouver 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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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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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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No 4. Maryam Alley.Pashazohri(South Kamrankeh)Street

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Fax**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

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**

Iran University of Medical Sciences

Full name of responsible person

Seyed Abbas Motevalian

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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

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

Dermatology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Position

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Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Latest degree

Medical doctor

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

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