Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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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+98 21 6655 1719

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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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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
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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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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
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Full name of responsible person
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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
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Fariba Khodadad
Position
resident
Latest degree
Medical doctor
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Person responsible for updating data

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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