Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Akbar Fotoohi
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Central University Organization, sixth floor, Vice Chancellor for Research and Technology, corner of Quds Street, Keshavarz Boulevard
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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
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
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Other areas of specialty/work
Cellular and Molecular Biology
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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
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