

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Evaluation of the effectiveness , satisfaction and complication of fractional CO2 laser and PRP in comparison with fractional CO2 laser in treatment of burn scar

Protocol summary

Study aim

Evaluation of the effectiveness , satisfaction and complication of fractional CO2 laser and PRP in comparison with fractional CO2 laser in 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 PRP, 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 PRP 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 PRP 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: **IRCT20200127046282N9**

Registration date: **2022-03-28, 1401/01/08**

Registration timing: **prospective**

Last update: **2022-03-28, 1401/01/08**

Update count: **0**

Registration date

2022-03-28, 1401/01/08

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 of the effectiveness , satisfaction and complication of fractional CO2 laser and PRP in comparisonwith fractional CO2 laser in treatment of burn scar

Public title
Evaluation of the effectiveness of fractional CO2 laser and PRP in comparisonwith fractional CO2 laser in 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 anticoagulants Patients with a history of underlying disease such as diabetes and autoimmune connective tissue disease that affect wound healing Patients with active viral infections 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
Patients and physicians will not know the type of treatment, but the evaluator will know the type of patient treatment. Therefore, the study will be conducted 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

2021-04-07, 1400/01/18

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1400.030

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

visio face

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
Intervention group: Patients with fractional CO2 laser with PRP 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
Skin and Stem Cell Research Center, 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
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, 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
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
Street address
No 4, Maryam Alley, South Kamraniyeh Street, Tehran
City
Tehran
Province
Tehran
Postal code
1937957511
Phone
+98 21 2665 7438
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

Street address

No 4, Maryam Alley, South Kamraniyeh Street, Tehran

City

Tehran

Province

Tehran

Postal code

1937957511

Phone

+98 21 2665 7438

Email

masoomehrohani@yahoo.com

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

Street address

No 4, Maryam Alley, South Kamraniyeh Street, Tehran

City

Tehran

Province

Tehran

Postal code

1937957511

Phone

+98 21 2665 7438

Email

sonazarebio@gmail.com

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