

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparison of Microneedeling Therapeutic Effect versus Fractional CO2 Laser in the Treatment of Burn Scars in Patients with Burn

Protocol summary

Study aim

The aim of this study is to Compare the Microneedeling Therapeutic Effect versus Fractional CO2 Laser in the Treatment of Burn Scars in burn patients referred to Rasoul e Akram Hospital.

Design

In this clinical trial study, 56 patients with burn scars who are referred to Rasoul-e-Akram Hospital are selected. Then, patients were randomly divided into two control and intervention groups.

Settings and conduct

In this research, 56 patients with burn scars who are referred to Rasoul-e-Akram Hospital were randomly divided into two control and intervention groups. A intervention group is treated with microneedeling in three sessions at intervals of 4 to 6 weeks and is followed up 3 months after the last session and a control group is treated with co2 fractional laser in three sessions at intervals of 4 to 6 weeks and is followed up 3 months after the last session.

Participants/Inclusion and exclusion criteria

Inclusion criteria: second and third degree burns; the age range is between 15 and 50 years old; lack of previous treatment procedures at the burning scar. Exclusion criteria: burns with higher grades; skin scars other than burns; symptoms of skin infection in affected areas; intolerance to each of the therapeutic interventions.

Intervention groups

A intervention group is treated with microneedeling in three sessions at intervals of 4 to 6 weeks and is followed up 3 months after the last session and a control group is treated with co2 fractional laser in three sessions at intervals of 4 to 6 weeks and is followed up 3 months after the last session.

Main outcome variables

Primary outcomes include: Contracture; height; Color; pliability; Vascularity assessed by the Vancouver burn scar assessment scale (VSS) and Patients' satisfaction level is assessed by the visual analogue scale (VAS) as a

secondary outcome.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140624018210N6**

Registration date: **2018-01-13, 1396/10/23**

Registration timing: **registered_while_recruiting**

Last update: **2018-01-13, 1396/10/23**

Update count: **0**

Registration date

2018-01-13, 1396/10/23

Registrant information

Name

Elham Behrangi

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6650 2040

Email address

behrangi.e@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Iran university of medical sciences

Expected recruitment start date

2017-04-21, 1396/02/01

Expected recruitment end date

2019-03-20, 1397/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of Microneedeling Therapeutic Effect versus Fractional CO2 Laser in the Treatment of Burn Scars in Patients with Burn

Public title
Comparison of Microneedeling Therapeutic Effect versus Fractional CO2 Laser in the Treatment of Burn Scars in Patients with Burn

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Second and third degree burns The age range is between 15 and 50 years old Lack of previous treatment procedures at the burning scar
Exclusion criteria:
 Burns with higher grades Skin scars other than burns Symptoms of skin infection in affected areas Intolerance to each of the therapeutic interventions

Age
From **15 years** old to **50 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
 Target sample size: **56**
 More than 1 sample in each individual
 Number of samples in each individual: **2**
 In each participant, the burn scar is divided into 2 parts, and one part is treated with microneedeling and one part is treated with a co2 fractional laser.

Randomization (investigator's opinion)
Randomized

Randomization description
Block randomization is a commonly used technique in clinical trial design to reduce bias and achieve balance in the allocation of participants to treatment arms. This method increases the probability that each arm will contain an equal number of individuals by sequencing participant assignments by block. The randomization unit is individual and randomization's tool is a statistical software.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, the Outcome assessor and data analyzer has been blinded. The Outcome assessor is people who are responsible for making assessments on outcomes or gathering data on outcome variables and does not know which treatment is performed on the burned scar. Data analyser is people who analyse the data collected during a trial and they do not know how to treat the

participants.

Placebo
Not 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 Hemmat highway
City
 Tehran
Province
 Tehran
Postal code
 1449614535

Approval date
2017-04-08, 1396/01/19

Ethics committee reference number
IR.IUMS.REC 1395.9411166003

Health conditions studied

1

Description of health condition studied
Burn scar

ICD-10 code
S00-T98

ICD-10 code description
injury, poisoning and certain other consequences of external causes

Primary outcomes

1

Description
Contracture

Timepoint
Before intervention, every 4 to 6 weeks for 3 session, three months after the last intervention

Method of measurement
Photography, clinical assesment

2

Description
Height

Timepoint

Before intervention, every 4 to 6 weeks for 3 session,
three months after the last intervention

Method of measurement

VSS scoring scale

3

Description

Color

Timepoint

Before intervention, every 4 to 6 weeks for 3 session,
three months after the last intervention

Method of measurement

VSS scoring scale

4

Description

Pliability

Timepoint

Before intervention, every 4 to 6 weeks for 3 session,
three months after the last intervention

Method of measurement

VSS scoring scale

5

Description

Vascularity

Timepoint

Before intervention, every 4 to 6 weeks for 3 session,
three months after the last intervention

Method of measurement

VSS scoring scale

Secondary outcomes

1

Description

Patient satisfaction

Timepoint

Before intervention, every 4 to 6 weeks for 3 session,
three months after the last intervention

Method of measurement

Photography, VAS scale

Intervention groups

1

Description

Intervention group: use of microneedeling, three
sessions at intervals of 4 to 6 weeks

Category

Treatment - Other

2

Description

Control group: use of fractional co2 laser, three sessions
at intervals of 4 to 6 weeks

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Rasoul Akram Hospital

Full name of responsible person

Dr Mahrokh Fotooei

Street address

Hazrat Rasoul Akram Hospital, Niayesh street,
Sattarkhan avenue, Tehran

City

Tehran

Province

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1313114456

Phone

+98 21 6435 2378

Email

mahrokh.fotooei@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr Mehrdad Eftekhari

Street address

Iran University of Medical Sciences, Shahid Hemmat
highway

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mehrdad.eftekhari@gmail.com

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

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

Hazrat Rasoul Akram Hospital

Full name of responsible person

Dr Mahrokh Fotooei

Position

Dermatology resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

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Web page address

Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Dr Mahrokh Fotooei

Position

Dermatology resident

Latest degree

Medical doctor

Other areas of specialty/work

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Research datas

When the data will become available and for how long

Starting 6 months after publication

To whom data/document is available

Dermatologists

Under which criteria data/document could be used

In the case of comparision with other similar trials

From where data/document is obtainable

Iran university of medical sciences

What processes are involved for a request to access data/document

Requests for data will be available to applicants upon examination and correspondence in the Dermatology

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hazrat Rasoul Akram Hospital

Full name of responsible person

Dr Elham Behrangi

Position

Dermatologist, Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

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