

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jul 2026

### Comparison of fractional co2 laser therapy alone and with its combination with topical timolol or topical insulin in the treatment of acne scar, A randomized controlled clinical trial

#### Protocol summary

##### Study aim

Comparison of fractional co2 laser therapy alone and with its combination with topical timolol or topical insulin in the treatment of acne scar

##### Design

A clinical trial with two treatment groups along with the control group (opposite side of the patient's face), with parallel groups, double-blind, randomized, phase 3 on 30 patients. Random Allocation Software is used for randomization.

##### Settings and conduct

This study is conducted on patients with acne scars who are referred to skin clinics of Shiraz University of Medical Sciences. Patients' lesions are randomly divided into two groups (right and left lesions). The plan is implemented in a double-blind manner.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. The patients with moderate to severe atrophic acne scarring and no inflammatory lesions 2. Age above 15 years old. Exclusion criteria: 2. Pregnant and lactating patients 2. Patients who have inflammatory lesions patients who have active Koebner-inducing diseases such as psoriasis and Lichen planus 3. Patients who have Asthma, atrioventricular blocks, sinus bradycardia, diabetes mellitus 4. Prior use of beta blockers, 5. The patients who have received Isotretinoin in the past three months.

##### Intervention groups

Group A lesions will receive fractional CO<sub>2</sub> laser therapy with distilled water on one side and the combination of fractional CO<sub>2</sub> laser therapy and topical Timolol Maleate 0.05% on the other side. Group B lesions will receive fractional CO<sub>2</sub> laser therapy with distilled water on one side and the combination of fractional CO<sub>2</sub> laser therapy and topical regular insulin on the other side. The mode of the fractional CO<sub>2</sub> device will be set to: Power: 12, Stack:2, Scanning dwell time: 500, and Spacing: 500. All of

the patients will be asked to participate in three sessions of laser therapy at three-week intervals.

##### Main outcome variables

Acne Scar Assessment Scale (ASAS)

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20150825023753N23**

Registration date: **2024-01-17, 1402/10/27**

Registration timing: **registered\_while\_recruiting**

Last update: **2024-01-17, 1402/10/27**

Update count: **0**

##### Registration date

2024-01-17, 1402/10/27

##### Registrant information

##### Name

Mohammad Mahdi Parvizi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3212 5592

##### Email address

parvizim@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-12-31, 1402/10/10

##### Expected recruitment end date

2024-06-19, 1403/03/30

##### Actual recruitment start date

empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
Comparison of fractional co2 laser therapy alone and with its combination with topical timolol or topical insulin in the treatment of acne scar, A randomized controlled clinical trial

**Public title**  
Comparison of fractional co2 laser therapy alone and with its combination with topical timolol or topical insulin in the treatment of acne scar

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
 The patients with moderate to severe atrophic acne scarring and no inflammatory lesions Age above 15 years old  
**Exclusion criteria:**  
 Pregnant and lactating patients Patients who have inflammatory lesions Patients who have active Koebner-inducing diseases such as psoriasis and Lichen planus Patients who have Asthma, atrioventricular blocks, sinus bradycardia, diabetes mellitus Prior use of beta blockers, The patients who have received Isotretinoin in the past three months.

**Age**  
From **15 years** old

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**

- Participant
- Investigator
- Outcome assessor
- Data analyser

**Sample size**  
Target sample size: **30**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
The randomization will follow a permuted block method, including 12 blocks of four, achieved by Random Allocation Software. In this regard, the lesions are divided into two groups A (right side of the face) and B (left side of the face). Dark-colored envelopes will be used to hide random allocation.

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
The used drugs will be poured into similar containers that will be tagged for A and B so that the resident and the patient will be ignorant of the applied medication. Only the secretary of the dermatology department will know the medication of each group.

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Medical School of Shiraz  
University of Medical Sciences

##### Street address

Medical School of Shiraz University of Medical  
Sciences

##### City

Shiraz

##### Province

Fars

##### Postal code

7134845794

#### Approval date

2023-10-16, 1402/07/24

#### Ethics committee reference number

IR.SUMS.MED.REC.1402.324

## Health conditions studied

### 1

#### Description of health condition studied

Acne scar

#### ICD-10 code

L90.5

#### ICD-10 code description

Scar conditions and fibrosis of skin

## Primary outcomes

### 1

#### Description

Severity of acne scar

#### Timepoint

At the beginning of the study and after two months

#### Method of measurement

Scale for Acne Scar Severity (SCAR-S),

### 2

#### Description

Acne Scar Assessment Scale

#### Timepoint

At the beginning of the study and after two months

#### Method of measurement

Acne Scar Assessment Scale (ASAS)

### 3

#### **Description**

Grading of scar

#### **Timepoint**

At the beginning of the study and after two months

#### **Method of measurement**

Goodman and Baron quantitative global scarring grading system (GBAQGS).

## **Secondary outcomes**

### 1

#### **Description**

Dermatologic Life Quality Index

#### **Timepoint**

At the beginning of the study and after two months

#### **Method of measurement**

Dermatologic Life Quality Index (DLQI) questionnaire

## **Intervention groups**

### 1

#### **Description**

Intervention group: Group A will receive fractional CO<sub>2</sub> laser therapy with distilled water on one side and the combination of fractional CO<sub>2</sub> laser therapy and topical Timolol Maleate 0.5% on the other side. The mode of the fractional CO<sub>2</sub> device will be set to: Power: 12, Stack: 2, Scanning dwell time: 700, and Spacing: 700.

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Intervention group: Group B will receive fractional CO<sub>2</sub> laser therapy with distilled water on one side and the combination of fractional CO<sub>2</sub> laser therapy and topical regular insulin on the other side. The mode of the fractional CO<sub>2</sub> device will be set to: Power: 12, Stack: 2, Scanning dwell time: 700, and Spacing: 700.

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Shahid Faghihi Dermatology Clinic

##### **Full name of responsible person**

Dr. Nasrin Saki

##### **Street address**

Shahid Faghihi Hospital, Zand Avenue

##### **City**

Shiraz

##### **Province**

Fars

#### **Postal code**

71348466114

#### **Phone**

+98 71 3212 5592

#### **Email**

nasrinsa85@yahoo.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Shiraz University of Medical Sciences

##### **Full name of responsible person**

Dr Mohammad Hashem Hashempur

##### **Street address**

Shiraz University of medical Sciences, Research vice,  
Zand Street

##### **City**

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##### **Province**

Fars

##### **Postal code**

7134814336

##### **Phone**

+98 71 3235 7252

##### **Email**

Hashempur@gmail.com

#### **Grant name**

#### **Grant code / Reference number**

#### **Is the source of funding the same sponsor organization/entity?**

Yes

#### **Title of funding source**

Shiraz 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**

Shiraz University of Medical Sciences

##### **Full name of responsible person**

Dr. Sara Sadat Alavizadeh

##### **Position**

Dermatology Resident

##### **Latest degree**

Specialist

##### **Other areas of specialty/work**

Dermatology

##### **Street address**

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Shiraz University of Medical Sciences  
**Full name of responsible person**  
Dr. Nasrin Saki  
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Traditional Medicine  
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nasrinsa85@yahoo.com  
**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Shiraz University of Medical Sciences  
**Full name of responsible person**  
Dr. Mohammad Mahdi Parvizi  
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Associate professor  
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mmparvizi@gmail.com

## 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

Yes - There is a plan to make this available

### Informed Consent Form

Yes - There is a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Yes - There is a plan to make this available

### Data Dictionary

Yes - There is a plan to make this available

### Title and more details about the data/document

Demographic data and the result of the clinical trial

### When the data will become available and for how long

One year later

### To whom data/document is available

Researchers

### Under which criteria data/document could be used

After the publication of the article based on the clinical trial, it will be possible to share the data. The recipients of the data can use the data by obtaining permission from the project managers. The managers of this project will allow the data to be used in secondary data analysis studies and systematic reviews.

### From where data/document is obtainable

Data requesters can submit their request by sending an email to each of the administrators that their names and emails have been entered into this system.

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

Data requesters can submit their request by sending an email to each of the administrators that their names and emails have been entered into this system.

### Comments

Data requesters can submit their request by sending an email to each of the administrators that their names and emails have been entered into this system.