

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Sep 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 CO₂ laser therapy with distilled water on one side and the combination of fractional CO₂ laser therapy and topical Timolol Maleate 0.05% on the other side. Group B lesions will receive fractional CO₂ laser therapy with distilled water on one side and the combination of fractional CO₂ laser therapy and topical regular insulin on the other side. The mode of the fractional CO₂ 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 CO₂ laser therapy with distilled water on one side and the combination of fractional CO₂ laser therapy and topical Timolol Maleate 0.5% on the other side. The mode of the fractional CO₂ 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 CO₂ laser therapy with distilled water on one side and the combination of fractional CO₂ laser therapy and topical regular insulin on the other side. The mode of the fractional CO₂ 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

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71348466114

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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

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Phone

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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

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

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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.