Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 CO۲ laser therapy with distilled water on one side and the combination of fractional CO۲ laser therapy and topical Timolol Maleate ۰.۵% on the other side. Group B lesions will receive fractional CO۲ laser therapy with distilled water on one side and the combination of fractional CO۲ laser therapy and topical regular insulin on the other side. The mode of the fractional CO۲ device will be set to: Power: ۱۲, Stack:۲, Scanning dwell time: ۷۰۰, and Spacing: ۷۰۰. 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)

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+98 71 3212 5592

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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 CO۲ laser therapy with distilled water on one side and the combination of fractional CO۲ laser therapy and topical Timolol Maleate ۰.۵% on the other side. The mode of the fractional CO۲ device will be set to: Power: ۱۲, Stack:۲, Scanning dwell time: ۷۰۰, and Spacing: ۷۰۰.
Category
Treatment - Drugs

2

Description
Intervention group: Group B will receive fractional CO۲ laser therapy with distilled water on one side and the combination of fractional CO۲ laser therapy and topical regular insulin on the other side. The mode of the fractional CO۲ device will be set to: Power: ۱۲, Stack:۲, Scanning dwell time: ۷۰۰, and Spacing: ۷۰۰.
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
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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
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7134814336
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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 updating data

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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.