

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 May 2026

Comparison of the efficacy of ablative fractional CO2 laser combined with punch elevation vs ablative fractional CO2 laser alone in treatment of depressed acne scar.

Protocol summary

Summary

Objectives: To compare the efficacy of Ablative Fractional CO2 Laser plus Punch elevation, with Ablative Fractional CO2 Laser alone for treatment of depressed acne scars. Design: Randomized, single blind, clinical trial. Setting and Conduct: In a dermatology clinic setting, 24 hours before first episode of laser therapy, eligible patients receive punch elevation on one side of the face chosen randomly. After 24 hours, both sides receive laser therapy with Fractional CO2 laser. Additionally, patients receive a repeat laser therapy session after one months. Outcome measures will be assessed by the use of serial photography at baseline, one, and four months after the first laser therapy session by two independent dermatologists blinded to the randomization. Major Inclusion and Exclusion criteria: Inclusion criteria: Age \geq 18 years; patient suffering from polymorphic and mixed acne scars; Fitzpatrick skin types 2 to4; informed consent for participation Exclusion Criteria: Presence of hypertrophic or Keloid scars; patient not returning for follow up visits; patient discontinuing intervention; suspect pregnancy. Intervention: One arm receives Fractional CO2 Laser plus punch elevation (with punch device gauges 1.5 to3.0) and the other receives Fractional CO2 Laser alone. Main Outcome Measures: Improvement in acne scar assessed by two independent dermatologists blinded to the randomization process and by means of serial photography.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014080218647N1**
Registration date: **2014-09-29, 1393/07/07**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-09-29, 1393/07/07

Registrant information

Name

Saeid Nouraei

Name of organization / entity

Isfahan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Deputy of research of Isfahan University of Medical Sciences.

Expected recruitment start date

2014-05-05, 1393/02/15

Expected recruitment end date

2014-11-06, 1393/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy of ablative fractional CO2 laser combined with punch elevation vs ablative fractional CO2 laser alone in treatment of depressed acne scar.

Public title

Efficacy of Fractional CO2 laser with or without punch elevation for treatment of depressed acne scars

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age ≥ 18 years; patient suffering from polymorphic and mixed acne scars; Fitzpatrick skin types 2 to 4; informed consent for participation. Exclusion Criteria: Presence of hypertrophic or Keloid scars; patient not returning for follow up visits; patient discontinuing intervention; suspect pregnancy.

Age

From 18 years old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 42

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

The side of the face to receive punch elevation was determined by a random process

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Deputy of research of Isfahan University of Medical Sciences, Hezar jerib Avenue, Isfahan.

City

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Postal code

Approval date

2013-10-30, 1392/08/08

Ethics committee reference number

392491

Health conditions studied

1

Description of health condition studied

acne scar

ICD-10 code

I90.5

ICD-10 code description

Scar conditions and fibrosis of skin

Primary outcomes

1

Description

Atrophic scar of acne

Timepoint

One and four months after the first laser therapy session

Method of measurement

by two independent dermatologists blinded to the randomization

Secondary outcomes

1

Description

Edema; Erythema; Pruritis; Hypo and Hyper pigmentation

Timepoint

After three days, one week, one month and four months the first laser therapy session

Method of measurement

Patient self administered checklist of overall satisfaction

2

Description

Clinical improvement of atrophic scar

Timepoint

One and four months after the first laser therapy session

Method of measurement

Patient self administered checklist of overall satisfaction

3

Description

Patients satisfaction

Timepoint

One and four months after the first laser therapy session

Method of measurement

Visual Analog Score

Intervention groups

1

Description

In one side of the face, 24 hours before the first session of laser treatment, punch elevation is done, followed by a session of Fractional CO2 ablative (Q ray, Diosis Inc, Seoul, Korea) with pulse energy: 25 mj per fixed 150 μ m diameter microbeam, density 400 MTZ/cm².

Category

Treatment - Devices

2

Description

On the other side of the face, without punch elevation (control group) a session of Fractional CO2 ablative (Q ray, Diosis Inc, Seoul, Korea) with pulse energy: 25 mj per fixed 150 µm diameter microbeam, density 400 MTZ/cm2 is administered.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

AL Zahra Hospital and Sedigheh tahere center

Full name of responsible person

Dr Saeid Nouraei

Street address

Department of Dermatology, Al Zahra Hospital, Isfahan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Isfahan University of Medical Sciences

Full name of responsible person

Dr Ebrahim Esfandiari

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Deputy of Research of Isfahan University of Medical Sciences, Hezar Jerib Avenue, Isfahan.

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for research of Isfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Skin disease and Leishmaniasis Research Center, Isfahan University of Medical Sciences, Isfahan, Ira

Full name of responsible person

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty