

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of the Effectiveness of Microneedling Therapy with CO2 Fractional Leaser therapy for the Treatment of Striae Distensa in Patients with Striae Distensae

Protocol summary

Study aim

Comparison of the efficacy of microneedling versus fractional leaser in treatment of striae

Design

The study will be performed a single-blind clinical trial on 40 patients with striae. In each patient, similar striae in shape and size and almost symmetrically at a surface of 5 x 5 cm² will be selected, and one side of the patient will be treated randomly by CO2 fractional laser method and the other side will be treated by microneedling method.

Settings and conduct

Shahid Dr. Faghihi Hospital, Each side will be randomly assigned to the treatment method using the "coin flip" method. Evaluators are blind. The study is one-way blind

Participants/Inclusion and exclusion criteria

In this study will be selected patients older than 15 and less than 50 years with striae including striae alba and striae rubra on abdomen, buttock, and flank lesions who had not received previous treatment for SD in the last two months; Pregnant women, breastfeeding mothers, patients taking immunosuppressive drugs, patients who are prone to forming keloid, patients who have received previous treatment for SD in the past 2 months, patients with Cushing's Syndrome or connective tissue diseases, patients who have vitamin derivatives A used up to 2 months prior to the study, patients who had a history of systemic or topical steroid use, filler injection, abdominal dermabrasion, or laser skin resurfacing in the SD area for the past 6-12 months, patients who had striae on their chest or arm, and patients with defective blood supply or diabetes mellitus or wound healing disorders.

Intervention groups

Each patient will be hypothetically divided into the right and left halves. One side of the patient will be treated with microneedling method and the other side will be treated with fractional CO2 laser method.

Main outcome variables

visual-analogue scale Patients satisfaction score
Dermatologist assessed improvement Lesions size

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120909010795N5**

Registration date: **2021-05-31, 1400/03/10**

Registration timing: **retrospective**

Last update: **2021-05-31, 1400/03/10**

Update count: **0**

Registration date

2021-05-31, 1400/03/10

Registrant information

Name

Nasrin Saki

Name of organization / entity

Dermatology Department, Shiraz university of medical sciences

Country

Iran (Islamic Republic of)

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+98 23 19049

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sakina@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-07, 1398/01/18

Expected recruitment end date

2019-12-21, 1398/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effectiveness of Microneedling Therapy with CO2 Fractional Laser therapy for the Treatment of Striae Distensa in Patients with Striae Distensae

Public title

Comparison of the Effectiveness of Microneedling Therapy with CO2 Fractional Laser therapy for the Treatment of Striae Distensa in Patients with Striae Distensae

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients older than 15 and less than 50 years Patients with striae including striae alba and striae rubra on abdomen, buttock, and flank lesions Patients had not received previous treatment for striae distance in the last two months

Exclusion criteria:

Pregnant women breastfeeding mothers Patients taking immunosuppressive drugs Patients who are prone to forming keloid Patients who have received previous treatment for SD in the past 2 months Patients with Cushing's Syndrome or connective tissue diseases Patients who have vitamin derivatives A used up to 2 months prior to the study Patients who had a history of systemic or topical steroid use, filler injection, abdominal dermabrasion, or laser skin resurfacing in the striae distance area for the past 6-12 months Patients who had striae on their chest or arm Patients with defective blood supply or diabetes mellitus or wound healing disorders

AgeFrom **15 years** old to **50 years** old**Gender**

Both

Phase

3

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **40**
More than 1 sample in each individual
Number of samples in each individual: **2**
Right and left (hypothetical line)

Randomization (investigator's opinion)

Randomized

Randomization description

Each side will be randomly assigned to the treatment method using the "coin flip" method. The microneedling method will be performed with the probability of a "Tail" and the fractional CO2 laser method with the probability of a "Head".

Blinding (investigator's opinion)

Single blinded

Blinding description

Treatment evaluations and scorings will be provided by two non-therapeutic dermatologists. Due to the different nature of treatment, the therapist and the patient are not blind, but the evaluators are blind and unaware of the treatment process.

Placebo

Not used

Assignment

Parallel

Other design features

Two common treatment modalities are discussed in this study.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shiraz University of Medical Sciences

Street address

Zand

City

Shiraz

Province

Fars

Postal code

14336 - 71348

Approval date

2019-02-18, 1397/11/29

Ethics committee reference number

IR.SUMS.MED.REC.1397.534

Health conditions studied**1****Description of health condition studied**

Striae rubra- striae alba

ICD-10 code

L90.6

ICD-10 code description

Linear dermal scars accompanied by epidermal atrophy that affects skin that is subjected to continuous stretching. They usually do not cause any significant medical problems, only cosmetic problems.

Primary outcomes**1****Description**

Dermatologist assessed improvement score

Timepoint

At baseline and 1 and 6 months after treatment
Method of measurement
Photography

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: It will be treated with microneedling method on a monthly basis.

Category

Treatment - Other

2

Description

Intervention group 2: It will be treated with fractional CO2 laser method on a monthly basis.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Faqhihi Hospital

Full name of responsible person

Dr. Nasrin Saki

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Younes Ghasemi

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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

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

Farzaneh Rahimi

Position

Resident

Latest degree

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Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity
Shiraz University of Medical Sciences
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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 clinical trial results

When the data will become available and for how long

6 months later

To whom data/document is available

Researchers

Under which criteria data/document could be used

After publication of the extracted article of the clinical trial

From where data/document is obtainable

Sending email to the researchers

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

Sending the request via the email

Comments