

# 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 cm<sup>2</sup> 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)

##### Phone

+98 23 19049

##### Email address

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

**Age**From **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

##### Street address

Zand street

##### City

Shiraz

##### Province

Fars

##### Postal code

7134844119

##### Phone

+98 71 3212 5592

##### Fax

##### Email

faghihihsp@sums.ac.ir

##### Web page address

<https://faghihi.sums.ac.ir/>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Full name of responsible person

Dr. Younes Ghasemi

##### Street address

Zand street

##### City

Shiraz

##### Province

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##### Postal code

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##### Phone

+98 71 3230 5410

##### Email

ghasemiy@sums.ac.ir

##### 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

Medical doctor

##### Other areas of specialty/work

Dermatology

##### Street address

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raahimi.1365@gmail.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Full name of responsible person

Dr.Nasrin Saki

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Farzaneh Rahimi

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dermatology

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**Province**

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14336 - 71348

**Phone**

+98 71 3235 2559

**Email**

raahimi.1365@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 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**