Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of the Effectiveness of Microneedling Therapy with CO2 Fractional Leaser therapy for theTreatment 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)

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 Leaser therapy for theTreatment of Striae Distensa in Patients with Striae Distensae

Public title
Comparison of the Effectiveness of Microneedling Therapy with CO2 Fractional Leaser therapy for theTreatment 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 streching. 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

Fars

Postal code

14336 - 71348

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

Zand street

City

Shiraz

Province

Fars

Postal code

14336 - 71348

Phone

+98 71 3235 2559

Email

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
Dermatology

Street address
Zand street

City
Shiraz

Province
Fars

Postal code
14336 - 71348

Phone
+98 71 3235 2559

Email
sakina@sums.ac.ir

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

Street address
Zand street

City
Shiraz

Province
Fars

Postal code
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