

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Comparison of micro needle radio-frequency plus fractional co2 laser efficacy versus micro needle radio frequency device alone in treatment of stria alba

Protocol summary

Summary

stria alba are atrophic linear scars caused by skin tension during pregnancy or rapid weight gain. stria may cause disturbing cosmetic problems and in spite of all the different modalities that have been used in treatment of this condition there's no gold standard method of treatment introduced till present. micro needle radio-frequency devices have been used in treatment of various atrophic scars including stria alba and have shown promising results in treatment of this condition. this study is aimed to evaluate the efficacy of micro needle radio-frequency combined with co2 fractional laser in treatment of stria alba. A randomized, clinical trial was done on 6 young adults (27-40 Years) with clinically diagnosed stria alba (total stria count 96). The inclusion criteria were Age between 27 and 40 years old, stria alba on the abdomen, buttocks, thighs, knees, calves and flanks and skin photo-type III and exclusion criteria were pregnancy, breastfeeding, stria alba on the chest or shoulders or arms, positive history of treatment with systemic or topical corticosteroids and patients with cushing or ehlers-danlos syndrome. The patients stria were divided into two groups using table of randomization. (Side A: treated by micro needle Radio-frequency combined with fractional co2 laser and Side B: Treated only by micro needle Radio-frequency device.) Side A stria were treated with 1 session of fractional co2 laser followed by 3 sessions of micro needle radio-frequency laser and again 1 last session of co2 fractional laser. in contrast Side B stria were treated with 3 sessions of micro needle radio-frequency laser alone. each treatment sessions were 2 weeks apart. all the lesions were photographed before treatment and 1 month after treatment completion and changes in surface area of stria were analyzed with pictzar software. also all pictures were evaluate by two unrelated

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014101519543N1**

Registration date: **2014-11-28, 1393/09/07**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-11-28, 1393/09/07

Registrant information

Name

Shadi Behfar

Name of organization / entity

Isfahan university of medical sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Isfahan University of Medical Sciences

Expected recruitment start date

2014-01-10, 1392/10/20

Expected recruitment end date

2014-04-09, 1393/01/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of micro needle radio-frequency plus fractional co2 laser efficacy versus micro needle radio frequency device alone in treatment of stria alba

Public title

Treatment of stria alba by micro needle radio-frequency device

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:stria alba on the abdomen, buttocks, thighs, knees, calves and flanks; skin photo-type III; negative history of previous stria treatment Exclusion criteria: pregnancy; breastfeeding; history of previous stria treatment; stria alba on the chest or shoulders or arms; positive history of treatment with systemic or topical corticosteroids; patients with cushing or ehlers-danlos syndrome; positive history of treatment with oral isotretinoin or filler injection over last year; history of dermabrasion or laser skin resurfacing therapy over last year;

Age

From **27 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **96**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezar Jarib Ave.

City

Isfahan

Postal code**Approval date**

2014-01-07, 1392/10/17

Ethics committee reference number

393433

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

striae alba

ICD-10 code

L90.6

ICD-10 code description

Striae atrophicae

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

Stria alba lesions

Timepoint

Base line, weeks 12, weeks 20

Method of measurement

Total Surface Area of stria alba and Visual Analogue Scale

Secondary outcomes**1****Description**

Side effects Of Laser treatments

Timepoint

every 2 weeks

Method of measurement

Visual clinical evaluation

Intervention groups**1****Description**

Side A stria were treated with 1 session of fractional co2 laser and followed by 3 sessions of micro needle radio-frequency treatment and 1 last session of fractional co2 laser.each laser treatment session was 2 weeks apart from each other.before each session lidocain cream were used on treatment area for about 60 min to achieve proper anesthesia.after each treatment the mupirocin and zinc oxide ointment were applied on the area and Vaseline gauze were used to dressing the treated area.total treatment period was 8 weeks and evaluation were done on baseline and 12 weeks of treatment. Follow up period was 3 months.

Category

Treatment - Devices

2

Description

Side B stria were treated with 3 sessions of micro needle radio-frequency treatment. each laser treatment session was 2 weeks apart from each other.before each session lidocain cream were used on treatment area for about 60 min to achieve proper anesthesia.after each treatment the mupirocin and zinc oxide ointment were applied on the area and Vaseline gauze were used to dressing the treated area.total treatment period was 4 weeks and evaluation were done on baseline and 8 weeks of treatment. Follow up period was 3 months.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Novin laser Centre

Full name of responsible person

Street address

sheikh sadugh Ave.

City

Isfahan

2

Recruitment center

Name of recruitment center

skin and leishmania research centre

Full name of responsible person

Street address

khorram Ave.

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Isfahan University of Medical Sciences

Full name of responsible person

Dr. Ebrahim Esfandiari, Vice Chancellor for research, Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezar Jarib Ave.

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Isfahan

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, 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

Isfahan University of Medical Sciences

Full name of responsible person

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Position

Resident of Dermatology/MD.

Other areas of specialty/work

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Web page address**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