

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

Comparison of the effect of combination microneedling and topical basic fibroblast growth factor with microneedling alone in the improvement of stria distensae

Protocol summary

Study aim

Comparison of the effect of combination microneedling and topical BFGF with microneedling alone in the improvement of stria distensae

Design

This study is a assessor-blinded randomized controlled, pilot clinical trial with parallel pattern.

Settings and conduct

The patients will be enrolled from the patients who are referred to outpatient dermatology clinics of Shahid Faghihi and Imam Reza clinics by consecutive sampling method.

Participants/Inclusion and exclusion criteria

The inclusion criteria of the study will be patients between 18 and 60 years old. The exclusion criteria of the study will be patients younger than 18 years or older than 60 years, pregnant or lactating women, diabetic, hypertension, hypothyroidism, hyperthyroidism, immunosuppressed patients, also patients who received stria treatment 3 months ago or have infection on the stria.

Intervention groups

Group A will receive microneedling monthly with topical bFGF for three months with a frequency of twice daily and group B will be undergo microneedling alone for three months with one-month intervals.

Main outcome variables

Clinical improvement of striae with global aesthetic improvement scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220924056033N1**

Registration date: **2022-10-07, 1401/07/15**

Registration timing: **prospective**

Last update: **2022-10-07, 1401/07/15**

Update count: **0**

Registration date

2022-10-07, 1401/07/15

Registrant information

Name

Rahil Hamedpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3234 4997

Email address

anisa1370@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-10-23, 1401/08/01

Expected recruitment end date

2023-03-19, 1401/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of combination microneedling and topical basic fibroblast growth factor with microneedling alone in the improvement of stria distensae

Public title

Effect of microneedling and topical basic fibroblast growth factor in treatment of stretch marks

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients between 18 and 60 years old

Exclusion criteria:

Pregnant women Lactating women Diabetic Hypertension Hypothyroidism Hyperthyroidism Immunosuppressed patients Patients who received stria treatment 3 months ago or have infection on the stria

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

The study groups are divided into two groups A and B using random allocation software using the permutation block method. Group A is assigned to microneedling and local fibroblast growth factor intervention group, and group B is assigned to microneedling intervention alone. Considering that patients enter the plan from number 1 to 30 in order; The colleague entered the study patients in the order of referral in the relevant intervention group and this order is maintained until the end of the study. Dark colored envelopes are used to hide the order of randomization codes.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this plan, the patients are aware of the type of intervention because patients in one group (group A) receive an invasive intervention (microneedling) along with a drug (local fibroblast growth factor) that cannot be used as a placebo, and the other group (group A) B receives only microneedling. However, the clinical assessment is not aware of the type of study and only recognizes patients with labels A and B, and the design is assessor blind in this regard.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Zand street, Shahid Faghihi hospital

City

Shiraz

Province

Fars

Postal code

7173776773

Approval date

2022-09-11, 1401/06/20

Ethics committee reference number

IR.SUMS.MED.REC.1401.326

Health conditions studied

1

Description of health condition studied

Stria distensa

ICD-10 code

L90.6

ICD-10 code description

Striae atrophicae

Primary outcomes

1

Description

Clinical improvement stria

Timepoint

Patients will be visited 4 times, 0, 1, 2, 5 month

Method of measurement

The GAIS(Global Aesthetic Improvement Scale) is measured as follows:Grade 0: worsening of lesions Grade1: No change (< 25% improvement)Grade 2: Improved (25-50% improvement)Grade 3: Much improved (51-75% improvement)Grade 4: Very much improved (76-100% improvement)

Secondary outcomes

1

Description

Stria size reduction

Timepoint

Patients will be visited 4 times, 0, 1, 2, 5 month

Method of measurement

Rate of width reduction (%)=Baseline width-Follow upwidth/Baseline width ×100

2

Description

Stria color

Timepoint

Patients will be visited 4 times, 0, 1, 2, 5 month

Method of measurement

Melanin index is measured by SkinColorCatch colorimeter (Delphin, Finland) and is presented as average of .3 points measure

3

Description

Patient satisfaction

Timepoint

Patients will be visited 4 times, 0, 1, 2, 5 month

Method of measurement

Patient satisfaction is assessed by a 5 point scale: 4: Extremely satisfied 3: Very satisfied 2: satisfied 1: Slightly satisfied 0: Not satisfied

Intervention groups

1

Description

Intervention group: Combination of microneedling and Basic Fibroblast Growth Factor (BFGF) in the treatment of stria distensae (each month three sessions)

Category

Treatment - Surgery

2

Description

Control group: Use of microneedling alone in the treatment of stria distensae (each month three sessions)

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Faghihi hospital

Full name of responsible person

Rahil Hamedpour

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Zand street, Shahid Faghihi hospital

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Phone

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Email

anisa1370@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr Mahtab Memarzadeh

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7134814336

Phone

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Email

vcrdep@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

Rahil Hamedpour

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

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Person responsible for scientific inquiries

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Full name of responsible person
Rahil Hamedpour

Position
Resident

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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is not information any more

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available