

# 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

#### Street address

Zand street, Shahid Faghihi hospital

#### City

Shiraz

#### Province

Fars

#### Postal code

7173776773

#### Phone

+98 71 3235 4997

#### 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

#### Street address

Zand street, Shiraz university medical science

#### City

Shiraz

#### Province

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#### Postal code

7134814336

#### Phone

+98 71 3235 7282

#### 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

#### Street address

Zand street, Shahid Faghihi hospital

#### City

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Shiraz University of Medical Sciences  
**Full name of responsible person**  
Rahil Hamedpour  
**Position**  
Resident  
**Latest degree**  
Medical doctor  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Shiraz University of Medical Sciences  
**Full name of responsible person**  
Rahil Hamedpour  
**Position**

Resident  
**Latest degree**  
Medical doctor  
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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