

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 May 2026

### Comparison of the effect of nanofat graft with microneedling in the clinical improvement of striae distensae

#### Protocol summary

##### Study aim

Determination of the effectiveness of nanofat grafting in comparison with microneedling in the treatment of striae distensae

##### Design

Phase 3, parallel group, clinical trial, with consecutive sampling, including 20 patients, single blinded, computerized randomized with permuted blocks

##### Settings and conduct

The study is conducted in the Imam Reza laser clinic of Shiraz University of Medical Sciences randomly with nanofat grafting in one side (one session at the beginning of study) and microneedling in the other side (3 session once monthly). The patients are assessed at the beginning of treatment, monthly visits for microneedling and 6 months after the first visit by photography and colorimetry. The investigator is blind to the type of treatment.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: patients of 18 to 60 years of age; bilateral striae distensae (alba and rubra); site on the abdomen, buttock, calves, thighs, and arms Exclusion criteria: pregnancy; lactation; body mass index  $\leq$  22; history of nickel hypersensitivity; history of treatment for striae in the recent one year; history of hypertrophic scar or keloid formation; active infections on the study area; severe underlying internal diseases; history of hypercoagulation states; Consumption of immunosuppressant drugs, systemic retinoids, corticosteroids, anabolic steroids in the recent 2 months; history of allergy to any ingredient of tumescent anesthetic solution; history of abdominoplasty; scar on the fat donor site; history of Cushing syndrome; polycystic ovary syndrome; body dysmorphic disorder

##### Intervention groups

Intervention group: Nanofat graft in the striae of one side of body one session at the beginning of study Control group: Microneedling of the striae of one side of body 3 session monthly

#### Main outcome variables

Clinical improvement of striae, measured by Global aesthetic improvement scale

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20140212016557N10**

Registration date: **2022-01-22, 1400/11/02**

Registration timing: **registered\_while\_recruiting**

Last update: **2022-01-22, 1400/11/02**

Update count: **0**

##### Registration date

2022-01-22, 1400/11/02

##### Registrant information

##### Name

Mozhdeh Sepaskhah

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 712125239

##### Email address

sepaskhah@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-01-10, 1400/10/20

##### Expected recruitment end date

2023-03-20, 1401/12/29

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of the effect of nanofat graft with microneedling in the clinical improvement of striae distensae

**Public title**

Effect of nanofat injection in the treatment of stretch marks

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

patients of 18 to 60 years of age bilateral striae distensae (alba and rubra) site on the abdomen, buttock, calves, thighs, and arms

**Exclusion criteria:**

pregnancy lactation body mass index less than or equal to 22 history of nickel hypersensitivity history of treatment for striae in the recent one year history of hypertrophic scar or keloid formation active infections on the study area severe underlying internal diseases history of hypercoagulation states Consumption of immunosuppressant drugs, systemic retinoids, corticosteroids, and anabolic steroids in the recent 2 months history of allergy to any ingredient of tumescent anesthetic solution history of abdominoplasty scar on the fat donor site history of Cushing syndrome history of polycystic ovary syndrome body dysmorphic disorder

**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: **20**

More than 1 sample in each individual

Number of samples in each individual: **2**

One side of the body is allocated in the nanofat grafting group and the other side in the microneedling group.

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The participants were randomized using permuted block randomization (size of each block: 4), in individual units, using random allocation software. The output of software is a table that determines the right or left side undergoes nanofat grafting.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

Due to the different treatment methods in two sides, the participants cannot be blinded. Principle investigator, and care provider physician are also aware of the the

side undergoing nanofat grafting. But, outcome assessors are not aware of the side undergoing nanofat grafting in each patient.

**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**

Shiraz University of Medical Sciences, Zand St., Shiraz. Iran

**City**

Shiraz

**Province**

Fars

**Postal code**

7134845794

**Approval date**

2021-12-20, 1400/09/29

**Ethics committee reference number**

IR.SUMS.MED.REC.1400.501

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

Striae distensae

**ICD-10 code**

L90.6

**ICD-10 code description**

Striae atrophicae

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

Clinical improvement of striae

**Timepoint**

The patients will be assessed in 3 monthly visits for microneedling, and 6 months after the first visit.

**Method of measurement**

Global aesthetic improvement scale, measured as: Grade 0: Worsening of lesions; Grade 1: 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

Striae size reduction

#### Timepoint

3 monthly visits for microneedling, and 6 months after the first visit

#### Method of measurement

Percentage of striae width reduction

### 2

#### Description

Striae color

#### Timepoint

At the beginning of treatment, 3 monthly visits for microneedling, and 6 months after the first visit

#### Method of measurement

Pigment index is measured by colorimetric device

### 3

#### Description

Dermoscopic features of striae

#### Timepoint

At the beginning of treatment, 3 monthly visits for microneedling, and 6 months after the first visit

#### Method of measurement

Dermatoscopic features like color, vascularity, width, and texture of striae

### 4

#### Description

Patient satisfaction

#### Timepoint

At the end of treatment

#### Method of measurement

A 5-point scale. 4: Extremely satisfied, 3:Very satisfied, 2: satisfied, 1: Slightly satisfied, 0: Not satisfied

### 5

#### Description

Pain during treatment

#### Timepoint

At the 3 sessions of monthly treatment

#### Method of measurement

Pain illustrated numerical rating scale

## Intervention groups

### 1

#### Description

Intervention group: Nanofat grafting in the striae of one side of the body (one session at the beginning of study)

#### Category

Treatment - Surgery

### 2

#### Description

Control group: microneedling in striae of one side of the body (3 session monthly)

#### Category

Treatment - Surgery

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Laser clinic, Imam Reza clinic

##### Full name of responsible person

Mozhdeh Sepaskhah

##### Street address

Laser clinic, Imam Reza clinic, Namazi Sq.

##### City

Shiraz

##### Province

Fars

##### Postal code

7134814734

##### Phone

+98 71 3212 7001

##### Email

sepaskhah@sums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Full name of responsible person

Dr Mahtab Memar zade

##### Street address

Research Council, Shiraz University of Medical Sciences, Zand St., Shiraz, Iran

##### City

Shiraz

##### Province

Fars

##### Postal code

7134814336

##### Phone

+98 71 3235 7282

##### Email

vcrdep@sums.ac.ir

#### Grant name

#### Grant code / Reference number

22872

#### 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

**Province**

Fars

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7134844119

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sepaskhah@sums.ac.ir

**Web page address****Person responsible for general inquiries****Contact****Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Mozhdeh Sepaskhah

**Position**

Associate professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Dermatology

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**Latest degree**

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**Other areas of specialty/work**

Dermatology

**Street address**

Shiraz University of Medical Sciences, Zand St, Shiraz, Iran

**City**

Shiraz

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**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