

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 Jun 2026

### Comparison of the therapeutic effect of the combination of Erbium YAG laser and stromal vascular fraction (SVF), the combination of Erbium YAG laser and platelet-rich plasma (PRP) and Erbium YAG laser alone in the treatment of striae

#### Protocol summary

##### Study aim

Comparison of the therapeutic effect of the combination of Erbium YAG laser and stromal vascular fraction (SVF), the combination of Erbium YAG laser and platelet-rich plasma (PRP) and Erbium YAG laser alone in the treatment of striae

##### Design

Clinical trial with control group, with parallel groups, double-blind, randomized with sealed envelopes, phase 2-3 on 10 patients (30 lesions)

##### Settings and conduct

In this study, 10 patients with at least three striae will be treated with Erbium YAG Laser in one session. Then, in the same session, one side is randomly injected with SVF, one side is injected with PRP, and the third side is injected with placebo. Injections are done with syringes of the same shape and color, and the patient, as well as the doctor evaluating the results and the statistician are blinded.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: The diagnosis of stria distensa based on the diagnosis of a dermatologist, Age less than 50 years and more than 18 years Exclusion criteria: Using any treatment method to remove striae in the last three months, Presence of lesions and skin diseases such as skin cancer or infections, Presence of collagen vascular diseases, Pregnancy and lactation, Using steroids or immunosuppressive drugs

##### Intervention groups

3 groups: combination of Erbium YAG laser and stromal vascular fraction (SVF), the combination of Erbium YAG laser and platelet-rich plasma (PRP) and Erbium YAG laser alone

##### Main outcome variables

Examining the level of effectiveness based on the Vancouver scale

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220322054341N2**

Registration date: **2023-01-20, 1401/10/30**

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

Last update: **2023-01-20, 1401/10/30**

Update count: **0**

##### Registration date

2023-01-20, 1401/10/30

##### Registrant information

##### Name

masoumeh rohaninasab

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6435 2421

##### Email address

rohaninasab.m@iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-01-14, 1401/10/24

##### Expected recruitment end date

2023-02-09, 1401/11/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Comparison of the therapeutic effect of the combination of Erbium YAG laser and stromal vascular fraction (SVF), the combination of Erbium YAG laser and platelet-rich plasma (PRP) and Erbium YAG laser alone in the treatment of striae

### Public title

The effect of erbium laser in striae

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

The diagnosis of stria distensa based on the diagnosis of a dermatologist Age less than 50 years and more than 18 years

#### Exclusion criteria:

Using any treatment method to remove striae in the last three months Presence of lesions and skin diseases such as skin cancer or infections Presence of collagen vascular diseases Pregnancy and lactation Using steroids or immunosuppressive drugs

### Age

From **18 years** old to **50 years** old

### Gender

Both

### Phase

2-3

### Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

### Sample size

Target sample size: **10**

More than 1 sample in each individual

Number of samples in each individual: **3**

Each patient must have at least three striae

### Randomization (investigator's opinion)

Randomized

### Randomization description

After being selected by available method, lesions are divided into 3 groups by simple randomization, so that among 30 sealed bags, one bag will be randomly selected for each lesion. Each bag contains the letter a, b, or c.

### Blinding (investigator's opinion)

Double blinded

### Blinding description

The injection of stromal vascular fraction (SVF), platelet-rich plasma (PRP) and normal saline was done with syringes of the same shape, the contents of which are not known, and the patient does not know which treatment group he is in. Also, the doctor evaluating the results and the statistician are blinded to the treatment group of the patient.

### Placebo

Used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Research Ethics Committee of School of Medicine, Iran University of medical sciences

##### Street address

School of medicine, Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran, Iran

##### City

Tehran

##### Province

Tehran

##### Postal code

1449614535

#### Approval date

2023-01-17, 1401/10/27

#### Ethics committee reference number

IR.IUMS.FMD.REC.1401.510

## 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

Pigmentation (color of the lesion)

#### Timepoint

3 months after the treatment

#### Method of measurement

Biometry with Colorimeter 4000, Multi Probe Adaptor System 5 (MPA5)

### 2

#### Description

Elasticity of the skin

#### Timepoint

3 months after the treatment

#### Method of measurement

Biometry with Cutometer, Multi Probe Adaptor System 580 (MPA580)

## Secondary outcomes

### 1

#### Description

Patient satisfaction

#### Timepoint

3 months after the treatment

#### Method of measurement

Based on patient global assessment score

### 2

#### Description

Complications

#### Timepoint

3 months after the treatment

#### Method of measurement

Using a checklist containing treatment complications including pain, erythema and edema

## Intervention groups

### 1

#### Description

Intervention group 1: combination of erbium Yag laser and intralesional injection of stromal vascular fraction (SVF). Erbium YAG laser usually selectively targets hydrous tissue with light of 2940 nm wavelength, and the residual thermal damage in the dermis leads to the accumulation and regeneration of collagen. SVF preparation: Mesenchymal stem cells are obtained by aspirating 20 to 40 cc of fat from the human thigh or abdomen during a surgical procedure (3 cm incision). The lipoaspirate is first washed thoroughly in phosphate-buffered saline before undergoing enzymatic digestion with collagenase to obtain a single cell suspension. After digestion, the centrifuged cell pellet (referred to as the Stromal Vascular Fraction (SVF)) is resuspended in StemMACS™ MSC Expansion Media before being serially filtered through 100-µm and then 40-µm nylon filters and the mononuclear cell fraction. The cell sample is counted and cultured in StemMACS MSC Expansion Media. MSCs will adhere to plastic surfaces within 24 hours, after which the media should be replaced with fresh StemMACS MSC Expansion Media. 2-3 cc of the prepared solution SVF are injected subcutaneously at one centimeter intervals using a 1cc syringe.

#### Category

Treatment - Other

### 2

#### Description

Intervention group 2: combination of erbium Yag laser followed by intralesional injection of platelet-rich plasma (PRP). Platelet-rich plasma: First, the anticoagulant drug is added with a 20-ml syringe at a ratio of 1 to 10 (one milliliter of anticoagulant per ten milliliters of the patient's blood sample). A 50-ml blood sample is then drawn from the patient's internal cubital vein. Time is

given for 10 seconds to ensure that the blood sample mixes with the anticoagulant drug. The tubes containing the above substance are centrifuged at 3000 rpm for 4 minutes. After centrifugation, there are three parts in the tube: a plasma part with few platelets, a tissue part and a red blood cell part. Since PRP is a combination of tissue and plasma, the red blood cells are separated from the kits. For final concentration, the separate parts containing PPP and buffy coat are centrifuged again at 3000 rpm for 4 minutes. The remaining PRP is then aspirated from each test tube and activated by adding calcium chloride (0.1 ml per 0.9 ml PRP) to finally obtain 6 ml of active PRP.

#### Category

Treatment - Other

### 3

#### Description

Intervention group 3: Combination of erbium Yag laser followed by intralesional injection of Normal Saline.

#### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Skin and Stem Cell Research Center of Tehran  
University of Medical Sciences

##### Full name of responsible person

Masoomeh Rohaninasab

##### Street address

Skin and Stem Cell Research Center of Tehran  
University of Medical Sciences, Maryam dead end,  
South Kamaranieh Street

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## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Skin and Stem Cell Research Center of Tehran  
University of Medical Sciences

##### Full name of responsible person

Mohammad Ali Nilforooshzadeh

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**Province**

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**Fax****Email**

info@skinstemcell.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Skin and Stem Cell Research Center of Tehran 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**

Iran University of Medical Sciences

**Full name of responsible person**

Masoumeh Roohaninasab

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dermatology

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**Full name of responsible person**

Masoomeh Roohaninasab

**Position**

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**Latest degree**

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**Other areas of specialty/work**

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**Position**

Resident

**Latest degree**

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**Other areas of specialty/work**

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zb.mahdi@gmail.com

**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**

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

make this available

**Statistical Analysis Plan**

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

**Informed Consent Form**

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

**Clinical Study Report**

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

**Analytic Code**

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

**Data Dictionary**

Not applicable