

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Jun 2026

### Evaluation and comparison of the effect of PRP and PRP with microneedling in the treatment of striae distensae

#### Protocol summary

##### Study aim

Evaluation and comparison of the effect of PRP and PRP with microneedling in the treatment of striae distensae

##### Design

This phase 1 study is performed on 30 patients with striae. Each patient is treated with PRP on the right half of the body and PRP with microneedling on the left side of the body for four sessions over 8 weeks, and their lesions are photographed before and after treatment, as well as patient satisfaction. Each party is evaluated from the treatment process (dissatisfied, almost satisfied, very satisfied) and also their histopathological results (thickness of epidermis, collagen and elastic fiber) before and three months after the treatment period and side effects are evaluated.

##### Settings and conduct

This project is performed in the Dermatology and Stem Cell Research Center of Tehran University of Medical Sciences and in the intervention groups, PRP on the right half of the body and PRP with microneedling on the left side of the body are transplanted.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: diagnosis of striae distensae based on the diagnosis of a dermatologist, patients' willingness to participate in the study; aged between 18 to 50.

Exclusion criteria: use of any treatment to eliminate striae in three months In the past, the presence of lesions and skin diseases such as skin cancer, wart, skin infection.

##### Intervention groups

Intervention group: Patients treated with PRP with microneedling on the left side of the body. Control group: Patients treated with PRP are placed on the right side of the body.

##### Main outcome variables

striae surface; side effects; patient's satisfaction

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200127046282N11**

Registration date: **2022-04-26, 1401/02/06**

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

Last update: **2022-04-26, 1401/02/06**

Update count: **0**

##### Registration date

2022-04-26, 1401/02/06

##### Registrant information

##### Name

Sona Zare

##### Name of organization / entity

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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2665 7438

##### Email address

sonazarebio@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-04-19, 1401/01/30

##### Expected recruitment end date

2022-07-21, 1401/04/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Evaluation and comparison of the effect of PRP and PRP with microneedling in the treatment of striae distensae

## Public title

Evaluation of the effect of PRP and PRP microneedling in the treatment of striae

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Diagnosis of striae distensae based on the diagnosis of a dermatologist Patient satisfaction with the study Age less than 50 years and more than 18 years

### Exclusion criteria:

Use any treatment to eliminate striae in the last three months Existence of skin lesions and diseases such as skin cancer wart Skin infection

## Age

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

## Gender

Both

## Phase

1-2

## Groups that have been masked

- Data analyser

## Sample size

Target sample size: **30**

## Randomization (investigator's opinion)

Not randomized

## Randomization description

## Blinding (investigator's opinion)

Single blinded

## Blinding description

The data analyzer will not know the type of treatment. Therefore, the study will be conducted in one blinds.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Tehran University of Medical Sciences

##### Street address

Tehran University of Medical Sciences, Keshavarz blvd.

##### City

Tehran

##### Province

Tehran

## Postal code

1417653761

## Approval date

2021-04-07, 1400/01/18

## Ethics committee reference number

IR.TUMS.MEDICINE.REC.1400.029

## Health conditions studied

### 1

#### Description of health condition studied

striae distensae

#### ICD-10 code

L90.6

#### ICD-10 code description

Atrophic disorder of skin, unspecified

## Primary outcomes

### 1

#### Description

striae size

#### Timepoint

before and 1 month after the intervention

#### Method of measurement

biometry

## Secondary outcomes

### 1

#### Description

Side effects

#### Timepoint

One week after treatment

#### Method of measurement

Questionnaire and visit

### 2

#### Description

Patient Satisfaction

#### Timepoint

one and three months after treatment

#### Method of measurement

Questionnaire

## Intervention groups

### 1

#### Description

Intervention group: Patients treated with PRP with microneedling on the left side of the body for four sessions over 8 weeks.

#### Category

Treatment - Other

**2**

**Description**

Control group: Patients treated with PRP are placed in the right half of the body for four sessions over 8 weeks.

**Category**

Treatment - Other

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Clinic of Skin and Stem cell Research Center of Tehran University of Medical Sciences

**Full name of responsible person**

Mohammad Ali Nilforoushzadeh

**Street address**

No 4, Maryam Alley, South Kamraniyeh Street, Tehran, Iran

**City**

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**Province**

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**Postal code**

1937957511

**Phone**

+98 21 2665 7438

**Email**

Nilforoosh@sina.tums.ac.ir

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

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

**Full name of responsible person**

Mohammad Ali Nilforoushzadeh

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**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, 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**

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

**Full name of responsible person**

Sona Zare

**Position**

Researcher

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Cellular and Molecular Biology

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sonazarebio@gmail.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

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

**Full name of responsible person**

Masoumeh Roohaninasab

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dermatology

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

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

**Full name of responsible person**

Sona Zare

**Position**

Researcher

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Cellular and Molecular Biology

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**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**

Not applicable

**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**

Not applicable

**Data Dictionary**

Not applicable