

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

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Postal code

1937957511

Phone

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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

Street address

No 4, Maryam Alley, South Kamraniyeh Street, Tehran

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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
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Full name of responsible person

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Position

Researcher

Latest degree

Ph.D.

Other areas of specialty/work

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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