

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Platelet Rich Plasma Versus Tranexamic Acid mesoneedling in Melasma Treatment: A Split Face Comparative Study

Protocol summary

Study aim

Platelet Rich Plasma Versus Tranexamic Acid mesoneedling in Melasma Treatment: A Split Face Comparative Study

Design

This phase 1 study is performed on 45 patients with melasma. At each session, the patient's right side receives the PRP along with the microneedling and the patient's left side receives the OAs along with the microneedling. This method will be done once a month for 4 sessions. All patients are photographed before digital therapy and 1 month after the fourth session by digital camera and Visophys. To determine the extent of improvement and compare the two groups, at the end of the study, photos of patients are examined by two neutral dermatologists. Patients' satisfaction and tolerance are also recorded and the results are compared.

Settings and conduct

This project is performed in the Skin and Stem Cell Research Center of Tehran University of Medical Sciences and in each session, the patient's right side receives PRP with microneedling and the patient's left side receives سید aaنگز with microneedling.

Participants/Inclusion and exclusion criteria

Inclusion criteria: People with melasma on the cheeks and other areas of the face. Exclusion criteria: Any complication that is related to the treatment process or is not tolerated by the patient, The patient does not want to continue treatment for any reason, Cancers, pregnancy, lactation, DVT, pulmonary embolism, stroke, Incidence of drug allergies, Occurrence of hypertrophic or colloidal scars at the treatment site

Intervention groups

In each session, one side receives PRP along with microneedling (intervention) and the other group receives PR with microneedling (control).

Main outcome variables

Melasma area brightness; side effects; Patient

satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200127046282N12**

Registration date: **2022-05-01, 1401/02/11**

Registration timing: **registered_while_recruiting**

Last update: **2022-05-01, 1401/02/11**

Update count: **0**

Registration date

2022-05-01, 1401/02/11

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

2022-09-06, 1401/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Platelet Rich Plasma Versus Tranexamic Acid mesoneedling in Melasma Treatment: A Split Face Comparative Study

Public title
PRP Versus Tranexamic Acid mesoneedling in Melasma Treatment

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
People with melasma on the cheeks and other areas of the face
Exclusion criteria:
Any complication that is related to the treatment process or is not tolerated by the patient The patient does not want to continue treatment for any reason Cancers, pregnancy, lactation, DVT, pulmonary embolism, stroke Incidence of drug allergies Occurrence of hypertrophic or colloidal scars at the treatment site

Age
No age limit

Gender
Both

Phase
1

Groups that have been masked

- Data analyser

Sample size
Target sample size: **45**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description
In each session, one group receives PRP along with microneedling and the other group receives PR with microneedling. Only the he data analyzer will not have information from the intervention groups.

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.1400.032

Health conditions studied

1

Description of health condition studied
Melasma

ICD-10 code
L81

ICD-10 code description
Other disorders of pigmentation

Primary outcomes

1

Description
Melasma area recovery rate

Timepoint
Before treatment and 1 month after the last session

Method of measurement
Visioface

Secondary outcomes

1

Description
side effects

Timepoint
One week after session

Method of measurement
Questionnaire and visit

2

Description
satisfaction

Timepoint
1 months after the last session

Method of measurement
Questionnaire and visit

Intervention groups

1

Description

Intervention group: At each session, the right side of the patient's face receives PRP along with microneedling.

Category

Treatment - Other

2

Description

Control group: At each session, the left side of the patient's face receives ohs with microneedling.

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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Email

Nilforoosh@sina.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Akbar Fotoohi

Street address

Keshavarz Boulevard, corner of Quds Street, Central
University Organization, sixth floor, Vice Chancellor
for Research and Technology

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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

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
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

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