

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

Evaluation of the effectiveness of microneedling with Tranexamic acid in comparison with microneedling with PRP in the treatment of melasma

Protocol summary

Study aim

Evaluation of the effectiveness of microneedling with Tranexamic acid in comparison with microneedling with PRP in the treatment of Melasma

Design

Parallel group randomized clinical trial, single-blinded with control group, 2nd phase on 23 patients. Randomization was carried out using coin toss method

Settings and conduct

The current study will be conducted on patients referred to the Dermatology clinic of Imam Khomeini Hospital of Ahvaz. In each session, Microneedling is done for one side of the face with PRP and with Tranexamic acid for the other side. The patient will not be aware of what medicine is injected for each side of her face, but the therapist is aware of this (single-blinded)

Participants/Inclusion and exclusion criteria

Inclusion criteria: 18 to 50 years old women with symmetric and bilateral facial Melasma. Exclusion criteria: Pregnant women and breastfeeding mothers, Having any history of coagulation disorders and thrombotic problems, Using anticoagulant and anticonvulsant drugs, Being allergic to study drugs and topical lidocaine, History of Melasma treatment during the past month, Active facial Herpes simplex lesions, Facial wart

Intervention groups

Intervention group 1: Performing Microneedling to a depth of 1.5 to 2 mm of the skin of one side of the face of the person under study with Tranexamic acid on 3 occasions with an interval of 3 weeks (random selection)
Intervention group 2: Performing Microneedling to a depth of 1.5 to 2 mm of the skin of the other side of the face of the person under study with PRP on 3 occasions with an interval of 3 weeks (random selection)

Main outcome variables

Melasma area and severity index score (MASI SCORE)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221025056287N1**

Registration date: **2022-12-09, 1401/09/18**

Registration timing: **registered_while_recruiting**

Last update: **2022-12-09, 1401/09/18**

Update count: **0**

Registration date

2022-12-09, 1401/09/18

Registrant information

Name

Havva Hajati

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 4282 9423

Email address

hajati.h@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-10-31, 1401/08/09

Expected recruitment end date

2022-12-30, 1401/10/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effectiveness of microneedling with Tranexamic acid in comparison with microneedling with PRP in the treatment of melasma

Public title

Comparison of microneedling with Tranexamic acid and PRP in treatment of Melasma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

18-50 years old women with Melasma Symmetrical and bilateral facial Melasma

Exclusion criteria:

Pregnant women Breastfeeding mothers Use of anticoagulants and anticonvulsants Being allergic to the study drugs and topical lidocaine History of Melasma treatment during the past month Active Herpes simplex lesions on the face Facial warts Any history of coagulation disorders and thrombotic problems

Age

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

Gender

Female

Phase

2

Groups that have been masked

- Participant

Sample size

Target sample size: **23**

More than 1 sample in each individual

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

Right and left side of the face

Randomization (investigator's opinion)

Randomized

Randomization description

We have two treatment groups of A and B in this study. For randomization, microneedling with Tranexamic acid is considered for the right side of patient's face and microneedling with PRP for the left side in group A. The treatment method in group B will be the opposite. This means that the right side of patient's face will be treated by microneedling with PRP and the left side by microneedling with Tranexamic acid. The treatment method of A and B will be determined using coin toss method.

Blinding (investigator's opinion)

Single blinded

Blinding description

The patient is not aware of how the treatment is assigned to the right and left side of her face, but the therapist knows that. This method is that PRP and tranexamic acid are drawn in insulin syringes with the same appearance covered with adhesive medical tape, so that the therapist is aware of their contents, but the patient is not aware of the type of drug used on the right and left side of the face.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Golestan Educational, Research and Treatment Center

Street address

Golestan Educational and Medical Center, Farvardin Ave, Golestan

City

Ahvaz

Province

Khouzestan

Postal code

6135733118

Approval date

2022-10-18, 1401/07/26

Ethics committee reference number

IR.AJUMS.HGOLESTAN.REC.1401.100

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 measuring index (MASI SCORE)

Timepoint

At the beginning of the study, the second and third sessions and 3 weeks after the completion of treatment sessions.

Method of measurement

Taking photo of the face with camera

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: performing Microneedling to a

depth of 1.5 to 2 mm of the skin using a 36-needle disposable cartridge with 200 mg Tranexamic acid in 3 times with an interval of 3 weeks on one side of the subject's face (random selection)

Category

Treatment - Other

2**Description**

Intervention group 2: performing Microneedling to a depth of 1.5 to 2 mm of the skin using a 36-needle disposable cartridge with 2 cc PRP prepared by a standard PRP kit in 3 times with an interval of 3 weeks on one side of the subject's face (random selection)

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam Khomeini Hospital of Ahvaz

Full name of responsible person

Nader Pazyar

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Imam khomeini educational hospital, Azadegan Ave.

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

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Ground floor, Vice chancellor of research, Ahvaz Jundishapour University of Medical Sciences, Daneshgahi Town, Ahvaz

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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

Ahvaz 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**

Ahvaz University of Medical Sciences

Full name of responsible person

Havva Hajati

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Position

Associate Professor

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Specialist

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Person responsible for updating data

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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