Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 severeity 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

Street address

Imam khomeini educational hospital, Azadegan Ave.

City

Ahvaz

Province

Khouzestan

Postal code

6193673111

Phone

+98 61 3222 2922

Email

Dr.Pazyar@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mehrnoosh Zakerkish

Street address

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

City

Ahvaz

Province

Khouzestan

Postal code

6135715794

Phone

+98 61 3336 2414

Fax

+98 61 3336 1544

Email

itc@ajums.ac.ir

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

Street address

Dermatology clinic, Imam Khomeini Hospital, Azadegan (24 metri) Ave.

City

Ahvaz

Province

Khouzestan

Postal code

6193673111

Phone

009832921873

Email

hajati.h@ajums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Nader Pazyar

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

Street address

Imam khomeini educational hospital, Azadegan Ave.

City

Ahvaz

Province

Khouzestan

Postal code

6193673111

Phone

+98 61 3222 2922

Email

Dr.Pazyar@gmail.com

Person responsible for updating data

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

Street address

Imam khomeini hospital, Dermatology clinic, Azadegan Ave.

City

Ahvaz

Province

Khouzestan

Postal code

6193673111

Phone

+98 61 3292 1873

Email

hajati.h@ajums.ac.ir

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