

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 2026

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

Protocol summary

Study aim

Evaluation of the effectiveness of microneedling with tranexamic acid in comparison with microneedling with vitamin C in the treatment of melasma

Design

A clinical trial with a control group, with parallel groups, one-way blind, randomized, phase 3 on 34 patients, a random number table is used for randomization.

Settings and conduct

Your study is currently a clinical trial that has not received a blind and future. It has been affiliated with the Medical School of Ahvaz University of Medical Sciences in Ahvaz Imam Khomeini Hospital since June 1400. At the first visit, after taking a history, each patient is examined with a wood lamp and the type of melasma (epidermal, dermal, mixed) is determined. This study is a randomized clinical trial comparing the two sides of the face, right and left, and our two groups compared both sides of the face. There are also 2 treatment groups A and B. Microneedling with a sterile disposable cartridge of 36 needles with a depth of 2 to 3 mm with the aim of achieving spot bleeding in the skin of the affected area in the horizontal, vertical and diagonal directions is done. Acid and 5 cc ampoules of vitamin C are poured directly on the skin for one side of the face and immediately after microneedling, 5 cc of each of the ampoules mentioned on sterile gas (SOAK) is placed on the skin for 15 minutes. This method is performed 3 times in 2 weeks (weeks 0, 2 and 4) and the result is compared in weeks 2, 4, 8 and 12.

Participants/Inclusion and exclusion criteria

Admission requirements: Women 18 to 50 years old with symmetrical and bilateral facial melasma who have read and signed the consent form.

Intervention groups

Performing microneedling with tranexamic acid on one side of the patient's face and also microneedling with

vitamin C on the other side of the face for people seeking melasma treatment

Main outcome variables

Treatment of melasma , Reduce pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210608051516N1**

Registration date: **2021-06-12, 1400/03/22**

Registration timing: **prospective**

Last update: **2021-06-12, 1400/03/22**

Update count: **0**

Registration date

2021-06-12, 1400/03/22

Registrant information

Name

Maryam Raeispour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3336 6086

Email address

raeispour.maryam@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-20, 1400/03/30

Expected recruitment end date

2021-10-22, 1400/07/30

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 vitamin C in the treatment of melasma

Public title
Microneedling with tranexamic acid and also microneedling with vitamin C for the treatment of melasma

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Women 18 to 50 years old with symmetrical and bilateral facial melasma
Exclusion criteria:
Pregnant women and breastfeeding mothers Taking oral contraceptive pills during the last 12 months and during the study Existence of any history of coagulation disorders and thrombotic problems Taking Medicines anticoagulants and anticonvulsants Existence of allergy to studied drugs and topical lidocaine History of melasma treatment in the past month Active facial herpes simplex lesions Facial warts

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

Gender
Female

Phase
2

Groups that have been masked

- Participant

Sample size
Target sample size: **34**

Randomization (investigator's opinion)
Randomized

Randomization description
For randomization in treatment method A for the right side of the patient's face, microneedling treatment with tranexamic acid and for the left side, microneedling and vitamin C treatment are considered, and in treatment method B, the opposite is true for the left side of the patient's microneedling treatment with tranexamic acid and side The right treatment is considered microneedling and vitamin C. Using the coin toss method, if the Heads is observed, treatment method A will be assigned and if the treatment method Tails B is assigned to the patient.

Blinding (investigator's opinion)
Single blinded

Blinding description
The study is one-sided blind in which only the participant is kept blind. The participant is aware of the type of drugs used but is not aware of how they are allocated to the left or right 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 Ahvaz Jundishapur University of Medical Sciences
Street address
13th floor, Block A ,Treatment and Medical Education ,Headquarters of the Ministry of Health, Iran TV St ,between South Flamek and Zarafshan ,Ghods Town (West), Tehran
City
Ahvaz
Province
Khouzestan
Postal code
1111111111

Approval date
2021-06-01, 1400/03/11

Ethics committee reference number
IR.AJUMS.HGOLESTAN.REC.1400.044

Health conditions studied

1

Description of health condition studied
Melasma

ICD-10 code
L81.1

ICD-10 code description
Chloasma

Primary outcomes

1

Description
Melasma area and severity index score (MASI SCORE)

Timepoint
It is done at the beginning of the study and weeks 2, 4, 8 and 12

Method of measurement
Face photography with camera

2

Description
Recovery rate of melasma lesions

Timepoint
It is done at the beginning of the study and weeks 2, 4, 8

and 12

Method of measurement

Face photography with camera

Secondary outcomes

1

Description

Patient satisfaction with melasma treatment

Timepoint

فارسىانگلیسى4 weeks after treatment

Method of measurement

questionnaire

Intervention groups

1

Description

Intervention group 1: Microneedling to a depth of 2 to 3 mm of the skin with tranexamic acid in 3 times with an interval of 2 weeks in one of the studied species (random selection)

Category

Treatment - Other

2

Description

Intervention group 2: Microneedling to a depth of 2 to 3 mm of skin with vitamin C in 3 times 2 weeks apart in the other species studied (randomly selected)

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahvaz Imam Khomeini Hospital

Full name of responsible person

Maryam Raeispour

Street address

Dermatology clinic, Emam Khomeini Hospital,
Azadegan (24 metri) Ave

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raeispour.maryam@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mehdi Ahmadi moghadam

Street address

Golestan , Ahvaz Jondishapur University of Medical
Sciences

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6135715794

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ahmadi-m@ajums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Vice Chancellor for Research, 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

Maryam Raeispour

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Participants' personal information including age, sex, complications and improvement of facial melasma before and after microneedling along with tranexamic acid and microneedling with vitamin C

When the data will become available and for how long

En Access period starts 6 months after the results are published

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Dermatologists Academic researchers Permitted analyzes: descriptive

From where data/document is obtainable

En E.mail : raeispour.maryam@gmail.com tel : 00989161168820

What processes are involved for a request to access data/document

The requested information will be provided to the applicant one month after receiving the email.

Comments