

# 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**  
Khuzestan  
**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

فارسینانگیسی 4 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

##### City

Ahvaz

##### Province

Khouzestan

##### Postal code

6155945813

##### Phone

+98 61 3336 6086

##### Email

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

##### City

Ahvaz

##### Province

Khouzestan

##### Postal code

6135715794

##### Phone

+98 61 3373 8383

##### Email

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

##### Street address

No. 12, East Motahhri Street, Kianpars

##### City

Ahvaz

##### Province

Khouzestan

##### Postal code

6155686448

**Phone**

+98 61 3336 6086

**Email**

raeispour.maryam@gmail.com

**Person responsible for scientific 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

**Street address**

No. 12, East 7th Street, Kianpars

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

6155686448

**Phone**

+98 61 3336 6086

**Email**

raeispour.maryam@gmail.com

**Person responsible for updating data**

**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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No. 12, East Motahhri Street, Kianpars

**City**

Ahvaz

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**Postal code**

6155686448

**Phone**

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**Email**

raeispour.maryam@gmail.com

**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**