

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of the Effectiveness of intradermal injected tranexamic acid 50mg/ml plus ascorbic acid 50mg/ml VS tranexamic acid 50mg/ml in the treatment of melasma: A split face comparative trial

#### Protocol summary

##### Study aim

Comparison of the efficacy of intradermal injected Tranexamic acid 50mg/ml with 50mg / ml Ascorbic acid on one side of the face with intradermal injected Tranexamic acid 50mg/ml and the other side of the face

##### Design

Comparative split face randomised clinical trial, with control group, parallel group, with 24 person in each group. RCT is in phase 3.

##### Settings and conduct

The study will be performed on patients who referred with facial melasma in Dermatology Clinic of Ahwaz Imam Khomeini Hospital. Patients are blinded about the type of medication injected.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 18-50 years old women; with bilateral facial melasma. Exclusion criteria: Pregnant and lactating women; Oral contraceptive pill consumption in 12 months ago during RCT; History of coagulopathy and thrombotic disorder; Anticoagulant and antiepileptic drug consumption; Sensitivity to tranexamic acid; History of treatment for melasma during 1 month ago; Active facial herpes simplex virus infection; Facial wart

##### Intervention groups

One side of the face is injected with tranexamic acid 50 mg / ml and ascorbic acid 50 mg / ml intradermally every other week for 12 weeks. The opposite side of the face is injected with tranexamic acid 50 mg / ml intradermally every other week for 12 weeks.

##### Main outcome variables

Melasma area and severity index; Patients satisfaction

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20191213045719N1**

Registration date: **2020-01-26, 1398/11/06**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-01-26, 1398/11/06**

Update count: **0**

##### Registration date

2020-01-26, 1398/11/06

##### Registrant information

###### Name

Seyedeh Nasrin Molavi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 61 5222 4052

###### Email address

molavi.n@ajums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-11-23, 1398/09/02

##### Expected recruitment end date

2020-08-23, 1399/06/02

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the Effectiveness of intradermal injected tranexamic acid 50mg/ml plus ascorbic acid 50mg/ml VS tranexamic acid 50mg/ml in the treatment of melasma: A

split face comparative trial

**Public title**

"Effect of Ascorbic acid in treatment of melasma"

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Women at the range of 18 to 50 years old patients with symmetrical bilateral melasma

**Exclusion criteria:**

Patient who is pregnant or in lactation period  
Patient who had taken oral contraceptive pill in 12 months ago  
Patient who has history of coagulopathy and thrombotic disorder  
Patient who is taking anticoagulant and antiepileptic drug  
Patient who has sensitivity to tranexamic acid  
Patient who has history of treatment for melasma during 1 month ago  
Patient who has active facial herpes simplex virus infection  
Patient who has facial wart

**Age**

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

**Gender**

Female

**Phase**

3

**Groups that have been masked**

- Participant
- Outcome assessor

**Sample size**

Target sample size: **24**

More than 1 sample in each individual

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

Right side of one person's face and left side of the same person's face

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Simple randomization will be done by coin toss. The coin will be thrown into the air several times (based on the number of study samples) and we will check which side is showing when it will land. If it will land from the head, the right side of the face will put in group A (tranexamic acid and ascorbic acid) and if it will land on the tail, the right side of the face will put in group B (tranexamic acid and placebo). Left side of the face. Then left side of the face will put in the other group.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

Due to the uniformity of the color and similarity of the appearance of the injected medication, participants and value assessment will be blinded to the medication given at any side of their faces.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Ahwaz Jondishapur University of Medical Sciences

**Street address**

Vice Chancellor for Research, Ahwaz Jondishapur University of Medical Sciences; Golestan Blvd

**City**

Ahwaz

**Province**

Khuzestan

**Postal code**

6193673166

**Approval date**

2019-11-23, 1398/09/02

**Ethics committee reference number**

IR.AJUMS.REC.1398.623

**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

**Timepoint**

Melasma area and severity index measured at base of trial and 4, 8, 12 and 24 weeks of trial

**Method of measurement**

Melasma area and severity index

**Secondary outcomes****1****Description**

Patient satisfaction

**Timepoint**

Measuring of patient satisfaction in 4, 8, 12 and 24 weeks of trial

**Method of measurement**

Satisfaction percentage questionnaire

## Intervention groups

### 1

#### Description

Intervention group: One side of the face is injected with Tranexamic acid 50 mg / ml and Ascorbic acid 50 mg / ml is given intradermally every other week for 12 weeks.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: The other side of the face is injected with tranexamic acid 50 mg / ml intradermally every other week for 12 weeks. Tranexamic acid is available in 500 mg ampoules at 5 cc. Ascorbic acid is available in 500 mg ampoules at 5 cc.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Imam Khomeini Hospital

##### Full name of responsible person

Doctor Seyedeh Nasrin Molavi

##### Street address

Imam khomeini Medicinal Academic Center,  
Azadegan Ave

##### City

Ahwaz

##### Province

Khuzestan

##### Postal code

6193673111

##### Phone

+98 61 3222 2922

##### Email

Molavi.n@ajums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Ahvaz University of Medical Sciences

##### Full name of responsible person

Mohammad Badavi

##### Street address

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

##### City

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##### Province

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6135715794

##### Phone

+98 61 3373 8383

##### Email

Molavi.n@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

Doctor Seyedeh Nasrin Molavi

##### Position

Resident

##### Latest degree

Medical doctor

##### Other areas of specialty/work

Dermatology

##### Street address

Dr Maashi office, Zaminha Ave, Kooye Abazar Ave,  
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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Ahvaz University of Medical Sciences

##### Full name of responsible person

Doctor Nader Pazyar

##### Position

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dermatology

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**Person responsible for updating data****Contact****Name of organization / entity**

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**Latest degree**

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**Other areas of specialty/work**

Dermatology

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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**

Undecided - It is not yet known if there will be a plan to make this available

**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**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available