

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jul 2026

### Comparison of efficacy of oral Tranexamic Acid with 4% topical hydroquinone in the treatment of melasma.

#### Protocol summary

##### Study aim

Comparison of Oral Transxamic Acid Effect with 4% Local Hydroquinone in the Treatment of Melasma

##### Design

Patients are placed under a wood lamp examination and the type of melasma (dermal, epithelial, mixed, unspecified) is determined. It is explained to the patient about the manner in which the work is carried out and they are willing to obtain consent to enter the study. patients placed randomized in one of the groups A, which included administration of the topical hydroquinone 4% of the company Bahuzan, making Iran (cream Hydroquinone 4%) that is applied locally in the morning and night, or Group B containing the transaxamic acid capsule 250 mg of Amin Pharmaceutical Company, Iran (Trancid capsule 250 milligram) every 12 hours. Before the onset of each patient, the intensity of melasma was measured by the formula of the Melasma area and severity index (MASI) score and recorded separately for each patient. Each patient is treated for 3 months in each group for a period of 3 months and is followed up during the period and advised to use sunscreen (without anti-pigment content). Within 1 month and 3 months after starting treatment, each patient is reassessed and calculated for the MASI score. The sample size will be 31 in each group.

##### Settings and conduct

The study was performed on patients with melasma referred to Dermatology Clinic of Ahvaz Imam Khomeini Hospital. Imam Khomeini Hospital, Ahvaz Hospital. Dermatology clinic Blinding process ; As a record of the score of the MASI by a single person( the person with no knowledge from the patient group that studied) during the study.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria : Patients with melasma aged 18 to 60 years. exclusion criteria: Patients with a history of coagulopathy, History of Thrombotic Problems Evidence for a thrombotic event, Using coagulant drugs, or

antiplatelets, such as aspirin or clopidogrel tablets, Pregnancy Lactation Concomitant use of contraceptives, The history of vitiligo or other pigmentation disorders, Trancexamic Acid Sensitivity History kidney disease, History of treatment for clarifying melasma during 3 months before the start of the study.

##### Intervention groups

Patients with melasma treated with Oral Transxamic Acid. Patients with melasma treated with topical hydroquinone 4%.

##### Main outcome variables

MASI SCORE. Sex Skin Phototype. Length of illness. family history. Type of melasma

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180111038311N1**

Registration date: **2018-04-03, 1397/01/14**

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

Last update: **2018-04-03, 1397/01/14**

Update count: **0**

##### Registration date

2018-04-03, 1397/01/14

##### Registrant information

##### Name

Samin Vala

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 3222 2818

##### Email address

vala.s@ajums.ac.ir

##### Recruitment status

**Recruitment complete**

## Funding source

### Expected recruitment start date

2017-08-23, 1396/06/01

### Expected recruitment end date

2018-05-22, 1397/03/01

### Actual recruitment start date

empty

### Actual recruitment end date

empty

### Trial completion date

empty

## Scientific title

Comparison of efficacy of oralTranexamicAcid with4% topical hydroquinone in the treatment of melasma.

## Public title

Efficacy of oralTranexamicAcid in melasma

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Patients with melasma with 18- 60 years old rang.

### Exclusion criteria:

Patients with coagulopathy Patients with thrombotic complications Any of thrombotic events Use of anticoagulant drugs or anti-platelet such as aspirin or Clopidogrel Pregnancy, lactation, concomitant use of contraceptives, The history of vitiligo or other pigmentation disorders, Trancexamic Acid Sensitivity History renal failure History of treatment for melasma with clarifying drugs in 3 months before the start of the study.

## Age

From **18 years** old to **60 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

## Sample size

Target sample size: **62**

## Randomization (investigator's opinion)

Randomized

## Randomization description

According to the quadrilateral permutation blocks, patients are randomly divided into two groups. This treatment is administered to both groups for 3 months.

## Blinding (investigator's opinion)

Not blinded

## Blinding description

As a record of the MASI score by a single person during the study, it does not have any information about the patient group being studied. During the treatment period, if the patient complains or does not want to

continue treatment, the study will be discontinued. During the sampling process, we will evaluate the MASI score as a baseline at the start of treatment, and at the 4th week - 12th and 3 months after the end of treatment, as well as at the end of the 3-month treatment, the patient's satisfaction with the treatment will be recorded in each group.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Ahvaz University of Medical Sciences

##### Street address

Ahvaz Jundishapur University of Medical sciences, Daneshgahi town, Ahvaz

##### City

Ahvaz

##### Province

Khouzestan

##### Postal code

6135715794

#### Approval date

2017-08-23, 1396/06/01

#### Ethics committee reference number

IR.AJUMS.REC.1396.714

## Health conditions studied

### 1

#### Description of health condition studied

Melasema

#### ICD-10 code

L81.1

#### ICD-10 code description

Chloasma

## Primary outcomes

### 1

#### Description

pigmentation

#### Timepoint

MASIS record before intervention - one month and three months after intervention

#### Method of measurement

MASI Score

## Secondary outcomes

### 1

#### Description

Gastrointestinal complications

#### Timepoint

before intervention - one month and three months after intervention

#### Method of measurement

Ask the patients

### 2

#### Description

Hypomenorea

#### Timepoint

before intervention - one month and three months after intervention

#### Method of measurement

Ask the patients

## Intervention groups

### 1

#### Description

Administration of the 250 mg Transxamic Acid Capsule Amin Pharmaceutical Company, Trancid capsule 250 milligram, is administered every 12 hours. On patients with melasma at the age of 18 to 60 years

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Administration of topical Hydroquinone 4% of Behzan Company, Iran (Cream Hydroquinone 4%), which is applied locally in the morning and night. On patients with melasma at the age of 18 to 60 years

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Dermatology Clinic of Ahvaz Imam Khomeini Hospital

##### Full name of responsible person

Samin Vala

##### Street address

Dermatology clinic, Eimam khomeini hospital, 24 metric Ave, Ahvaz

##### City

Ahvaz

##### Province

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##### Postal code

6193673111

#### Phone

+98 61 3222 2922

#### Email

saminvala@gmail.com

## 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, Ahvaz Jundishapur University of Medical Sciences, Daneshgahi town, Ahvaz

##### City

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6135715794

##### Phone

+98 61 3373 8383

##### Email

Research@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

Samin Vala

##### Position

Resident

##### Latest degree

Medical doctor

##### Other areas of specialty/work

Dermatology

##### Street address

Eimam khomeini hospital, 24 metric Ave, Ahvaz

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Ahvaz University of Medical Sciences  
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Reza Yaghoobi  
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professor  
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Specialist  
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## Person responsible for updating data

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**Name of organization / entity**  
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**Latest degree**  
Medical doctor

**Other areas of specialty/work**  
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**City**  
Ahvaz  
**Province**  
Khouzestan  
**Postal code**  
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vala.s@ajums.ac.ir

## 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

Yes - There is a plan to make this available

### Title and more details about the data/document

The total potential data can be shared after denationalization of people.

### When the data will become available and for how long

Start the access period 1 year after the results print.

### To whom data/document is available

Only available to scholars working in academia .

### Under which criteria data/document could be used

Only for statistical analysis or use in multi-center designs.

### From where data/document is obtainable

samin vala samINVALA@gmail.com 009891633114629

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

Send request via academic email. we will Send the data file within one month from the time of request.

### Comments