

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of therapeutic effect of oral and topical tranexamic acid in the treatment of patients with facial melasma receiving topical hydroquinone

#### Protocol summary

##### Summary

This study aimed to compare the therapeutic effect of oral and topical tranexamic acid in patients with melasma. The main inclusion criterion is the age between 20 and 70 years. The main exclusion criteria of the study are pregnancy; underlying skin disease; skin infection such as impetigo; the use of skin peeling therapies and a history of drug allergy. Among patients attending to dermatology clinic of Tabriz Sina Hospital with diagnosis of melasma, 90 patients will be divided in three groups of 30 subjects and will be studied. In the first group only hydroquinone cream, in the second group hydroquinone cream with tranexamic acid capsules orally, and in the third group hydroquinone cream and topical tranexamic acid will be used. Patients will be reviewed monthly and for each patient special forms will be filled out. Melasma severity depending on the extent of facial involvement, the degree of darkness and the homogeneity of the hyperpigmentation will be rated.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201411033566N7**

Registration date: **2014-11-20, 1393/08/29**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2014-11-20, 1393/08/29

##### Registrant information

##### Name

Hamide Azimi

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 1540 6612

##### Email address

azimih@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research, Tabriz University of Medical Sciences

##### Expected recruitment start date

2014-12-22, 1393/10/01

##### Expected recruitment end date

2015-04-21, 1394/02/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of therapeutic effect of oral and topical tranexamic acid in the treatment of patients with facial melasma receiving topical hydroquinone

##### Public title

Comparison of topical and oral treatments of melasma

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criterion: patients with facial melasma; patients between 20 and 70 years old. Exclusion criteria: pregnancy; underlying skin diseases; thyroid disease; history of drug allergy; previous use of contraceptives or

phenytoin; patients with uncontrolled hypertension; patients with skin infections such as Impetigo; a history of coagulation or thrombosis; skin peeling treatments to treat existing disease; persons aged less than 20 years and more than 70 years old.

#### **Age**

From **20 years** old to **70 years** old

#### **Gender**

Both

#### **Phase**

3

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **90**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

#### **Blinding (investigator's opinion)**

Not blinded

#### **Blinding description**

#### **Placebo**

Not used

#### **Assignment**

Parallel

#### **Other design features**

### **Secondary Ids**

empty

### **Ethics committees**

#### **1**

##### **Ethics committee**

###### **Name of ethics committee**

Ethics Committee of Tabriz University of Medical Sciences

###### **Street address**

Tabriz University of Medical Sciences, Daneshgah Sq.

###### **City**

Tabriz

###### **Postal code**

##### **Approval date**

2014-09-29, 1393/07/07

##### **Ethics committee reference number**

93105

### **Health conditions studied**

#### **1**

##### **Description of health condition studied**

Melasma

##### **ICD-10 code**

L81.1

##### **ICD-10 code description**

Chloasma

### **Primary outcomes**

#### **1**

##### **Description**

The extent of facial skin involvement in percentage

##### **Timepoint**

At the first visit and then monthly up to 3 months.

##### **Method of measurement**

Usin MASI scoring system

#### **2**

##### **Description**

degree of melasma darkness compairing to normal skin

##### **Timepoint**

At the first visit and then monthly up to 3 months.

##### **Method of measurement**

Usin MASI scoring system

#### **3**

##### **Description**

Homogeneity of the melasma hyperpigmentation

##### **Timepoint**

At the first visit and then monthly up to 3 months.

##### **Method of measurement**

Usin MASI scoring system

### **Secondary outcomes**

empty

### **Intervention groups**

#### **1**

##### **Description**

The first group will only be treated with hydroquinone 2% cream evey night for 12 weeks.

##### **Category**

Treatment - Drugs

#### **2**

##### **Description**

The second group will be treated with hydroquinone 2% cream every night and tranexamic acid capsules 250 mg PO/BID for 12 weeks.

##### **Category**

Treatment - Drugs

#### **3**

##### **Description**

The third group will be treated with hydroquinone 2% cream every night and topical tranexamic acid cream 500mg daily for 12 weeks.

##### **Category**

Treatment - Drugs

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Dermatology Clinic of Sina Hospital

**Full name of responsible person**

Anali Sadeghi

**Street address**

Dermatology ward, Sina Hospital, Azadi Ave.

**City**

Tabriz

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Vice chancellor for research, Tabriz University of Medical Sciences

**Full name of responsible person**

Ali Reza Ostad Rahimi

**Street address**

Vice chancellor for research, Tabriz University of Medical Sciences, Daneshgah Avenue, Daneshgah Square

**City**

Tabriz

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Vice chancellor for research, Tabriz University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

## Person responsible for general inquiries

### Contact

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Anali Sadeghi

**Position**

MD, resident of Dermatology

**Other areas of specialty/work**

**Street address**

Dermatology ward, Sina Hospital, Azadi Ave

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**Phone**

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**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Hamide Azimi

**Position**

Dermatologist/Associate professor

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Behzad Izadseresht

**Position**

Medical student

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*