

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jul 2026

### Comparison of the effect of topical Methimazole 5% versus topical Hydroquinone 4% on the improvement of melasma lesions

#### Protocol summary

Registration timing: **prospective**

##### Study aim

main goal of the study: comparison of topical 5% Methimazole and 4 % Hydroquinone effect on melasma

##### Design

Clinical trial with a control group in the same patient, without blinding and not randomized, phase 2-3 on 30 patients.

##### Settings and conduct

The studied patients are 30 patients with melasma and they visited the skin clinic of Sinai Hospital in the fall and winter of 1401. Methimazole 5% topical cream, which is formulated, is provided to the patients and they are asked to apply once a day to Apply this cream on the right side of your cheek and use 5% topical hydroquinone cream on the left side of your cheek.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria 1) Age above 18 years and below 50 years 2) informed consent to participate in the study 3) presence of melasma on both sides of the cheeks  
Exclusion criteria 1) having no consent to participate in the study 2) pregnancy or lactation 3) history of sensitivity to Tiamazoles 4) history of using other topical drugs for melanoma in past 3 months 5) thyroid dysfunction

##### Intervention groups

The formulated 5% topical methimazole cream is provided to the patients and they are asked to apply this cream once a day to the right side of their cheek and apply 5% topical hydroquinone cream to the left cheek. .

##### Main outcome variables

Severity of melasma lesions

Last update: **2023-02-21, 1401/12/02**

Update count: **0**

##### Registration date

2023-02-21, 1401/12/02

##### Registrant information

###### Name

Hamide Herizchi

###### Name of organization / entity

Tabriz University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 41 1336 4650

###### Email address

herizchih@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-03-06, 1401/12/15

##### Expected recruitment end date

2023-04-19, 1402/01/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the effect of topical Methimazole 5% versus topical Hydroquinone 4% on the improvement of melasma lesions

##### Public title

Comparison of topical 5% Methimazole and 4 %

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20091012002581N9**

Registration date: **2023-02-21, 1401/12/02**

Hydroquinone effect on melasma

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Age higher than 18 years and below 50 years Informed consent participate in the study Presence of melanoma in both sides of cheeks  
**Exclusion criteria:**  
Lack of consent to participate in the study Pregnancy or lactation History of sensitivity to Tiamazoles Thyroid dysfunction History of using other topical drugs for melanoma in past 3 months

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

**Gender**  
Both

**Phase**  
2-3

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **30**  
More than 1 sample in each individual  
Number of samples in each individual: **2**  
the patient uses the Methimazole cream in one side of cheek and Hydroquinone in other side as in control

**Randomization (investigator's opinion)**  
Not randomized

**Randomization description**

**Blinding (investigator's opinion)**  
Not blinded

**Blinding description**

**Placebo**  
Not used

**Assignment**  
Factorial

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Vice Chancellor for research of Tabriz University of Medical Sciences

##### Street address

Research centre , 3th floor, Central building number 2,Tabriz University of Medical Sciences,Golgasht street ,Tabriz

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

515431232

#### Approval date

2022-11-22, 1401/09/01

#### Ethics committee reference number

IR.TBZMED.REC.1401.771

## Health conditions studied

### 1

#### Description of health condition studied

melasma

#### ICD-10 code

L81.1

#### ICD-10 code description

Chloasma

## Primary outcomes

### 1

#### Description

Severity of melasma lesions

#### Timepoint

1, 4, 8 and 12 months after treatment

#### Method of measurement

Clinical examination and comparison of photos and use of Hemi Masi score

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: 5% topical methymazole cream that has been formulated in Tabriz University of Medical Sciences Faculty of Pharmacy, is provided to the patients and they are asked to apply this cream to the right side of their cheek once a day. Patients are followed up at intervals of 4, 8, and 12 weeks, and their recovery rate, satisfaction, and Masi score are checked for them. Thyroid function tests are also requested again in the 8th week. The side effects and recovery rate will be checked based on the mentioned cases at the end of the 12th week.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: 5% topical hydroquinone cream that has been formulated in Tabriz University of Medical Sciences Faculty of Pharmacy, is provided to the patients and they are asked to apply this cream to the right side of their cheek once a day. Patients are followed up at intervals of 4, 8, and 12 weeks, and their recovery rate, satisfaction, and Masi score are checked for them. Thyroid function tests are also requested again in the 8th week. The side effects and recovery rate will be checked based on the

mentioned cases at the end of the 12th week.  
**Category**  
Treatment - Drugs

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**  
Sina hospital  
**Full name of responsible person**  
Dr Hamideh Herizchi-Ghadim  
**Street address**  
Maralan street  
**City**  
Tabriz  
**Province**  
East Azarbaijan  
**Postal code**  
5163639888  
**Phone**  
+98 41 3541 2101  
**Email**  
Drherizchi@yahoo.com

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**  
Tabriz University of Medical Sciences  
**Full name of responsible person**  
Hamideh Herizchi - Ghadim  
**Street address**  
Maralan ( Azadi) street  
**City**  
Tabriz  
**Province**  
East Azarbaijan  
**Postal code**  
5163639888  
**Phone**  
+98 41 8236 3549  
**Email**  
Drherizchi@yahoo.com  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Tabriz 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**  
Tabriz University of Medical Sciences  
**Full name of responsible person**  
Dr Hamideh Herizchi- Ghadim  
**Position**  
Associate professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
dermatologist  
**Street address**  
Dermatology ward , Sina hospital,Azadi street, Tabriz  
**City**  
Tabriz  
**Province**  
East Azarbaijan  
**Postal code**  
5166614766  
**Phone**  
+98 41 1540 6612  
**Email**  
dr.herizchi@yahoo.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Tabriz University of Medical Sciences  
**Full name of responsible person**  
dr Hamideh Herizchi- Ghadim  
**Position**  
Associate professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
dermatologist  
**Street address**  
Dermatology ward, Sina hospital, Azadi street , Tabriz  
**City**  
Tabriz  
**Province**  
East Azarbaijan  
**Postal code**  
5166614766  
**Phone**  
+98 41 1540 6612  
**Email**  
dr.herizchi@yahoo.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Tabriz University of Medical Sciences

**Full name of responsible person**

Hamideh Herizchi Ghadim

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

dermatology

**Street address**

Dermatology clinic, Sina hospital, Maralan street ,  
Tabriz

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5163639888

**Phone**

+98 41 3541 2101

**Email**

herizchih@tbzmed.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**

No - There is not 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 data of the study are classified and coded so that  
the names of the people cannot be identified.

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

Access starts from the beginning of data collection  
November 1401

**To whom data/document is available**

For researchers in academic institutions

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

In order to use in other studies

**From where data/document is obtainable**

To me, Hamida Harizchi Ghadim, all the ways of  
communication have been mentioned in the previous  
section Priority through phone call , Email and then SMS  
Shaghayegh Babapoor through phone call, SMS and E-  
mail

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

After receiving the request via phone call or SMS and  
email, it will be sent within a week.

**Comments**