

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 2026

### Evaluation of Methimazole 5% cream effectiveness versus Hydroquinone cream 2% in patient with melasma, referred to Dermatology Clinic

#### Protocol summary

##### Summary

Objectives: This interventional study as a randomized double blind would be clinical trial of Evaluation of Methimazole 5% cream effectiveness versus Hydroquinone 2% cream to reduce melasma. Design: 50 patients with melasma in two groups of patients as controls and cases, each group consisted of 25 patients. Both treatment and advantages and disadvantages of each will be explained. Setting and conduct: At first patients will be asked to vote thyroid function tests. Cases will be treated with Methimazole 5% cream nightly for 8 weeks. The control group will be treated with Hydroquinone 2% cream nightly for 8 weeks. Inclusion criteria: Ages from 18 to 50; Normal to dry skin; without comedones Exclusion criteria: Absence of follow up by patients and not satisfied to continue; Complications such as allergy to topical agent; Pregnancy and lactation; Thyroid disease; Oral contraceptive pills use and other drugs that cause melasma Intervention: The response to treatment based on visioface images. Outcome measures variables: Data collection is done by forms of patient information concerning the patient information, age and co morbidity. Then patients will be reassessing to evaluate response to treatment visioface photography and MASI system. In order to ensure that the drug's effect on thyroid hormones, again, thyroid function tests for patients will be asked at the end of the period.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016073129145N1**  
Registration date: **2016-12-05, 1395/09/15**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-12-05, 1395/09/15

##### Registrant information

###### Name

Sedighe Naeji

###### Name of organization / entity

Iran University Of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 4401 1989

###### Email address

naeji.s@tak.iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research, Iran University of Medical Sciences.

##### Expected recruitment start date

2016-08-05, 1395/05/15

##### Expected recruitment end date

2016-11-20, 1395/08/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of Methimazole 5% cream effectiveness versus Hydroquinone cream 2% in patient with melasma, referred to Dermatology Clinic

##### Public title

Clinical trial of evaluation of Methimazole 5% cream effectiveness versus Hydroquinone cream 2% to reduce pregnancy spots (melasma)

##### Purpose

Treatment

### **Inclusion/Exclusion criteria**

Inclusion criteria: Ages from 18 to 50; Normal to dry skin; without comedones Exclusion criteria: Absence of follow up by patients and not satisfied to continue; Complications such as allergy to topical agent; Pregnancy and lactation; Thyroid disease; Oral contraceptive pills use and other drugs that cause melasma.

### **Age**

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

### **Gender**

Both

### **Phase**

2-3

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

*No information*

### **Sample size**

Target sample size: **50**

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

Randomized

### **Randomization description**

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

Double 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 Iran University of Medical Sciences

##### **Street address**

Iran University Of Medical Sciences, Adjacent to the Milad Tower, Hemat Highway, Tehran

##### **City**

Tehran

##### **Postal code**

##### **Approval date**

2015-11-30, 1394/09/09

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

IR.IUMS.REC.1394.27226

## **Health conditions studied**

### 1

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

melasma

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

L81.1

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

Chloasma

## **Primary outcomes**

### 1

#### **Description**

Hyperpigmentation of face skin

#### **Timepoint**

At first and 8 weeks after treatment

#### **Method of measurement**

Intensity of the darkening of the face skin compared to other areas of the face with visioface device.

## **Secondary outcomes**

### 1

#### **Description**

Satisfaction amount

#### **Timepoint**

After completion of treatment

#### **Method of measurement**

Comparison of reduction hyperpigmentation by patient, before and after treatment According to schedule

## **Intervention groups**

### 1

#### **Description**

Intervention group 1: Cases will be treated with Methimazole 5% topical cream once a night for 8 weeks.

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Intervention group 2: The control group will be treated with Hydroquinone topical cream 2% once a night for 8 weeks.

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Hazrat Rasool Akram Hospital

##### **Full name of responsible person**

Sedighe Naeji

##### **Street address**

Dermatology clinic, Hazrat Rasool Akram Hospital, Niayesh Steet, Shahr Aara, Sattarkhan Street, Tehran

##### **City**

Tehran

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Vice chancellor for research, Iran University of Medical Sciences

**Full name of responsible person**

Dr Seyed Ali Javad Mousavi

**Street address**

Iran University Of Medical Sciences, Adjacent to the Milad Tower, Hemat Highway, Tehran

**City**

Tehran

**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, Iran 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**

Iran University Of Medical Sciences

**Full name of responsible person**

Sedighe Naeji

**Position**

Dermatology Resident

**Other areas of specialty/work****Street address**

Dermatology department, Hazrat Rasool hospital, Niayesh Steet, Shahr Aara, Sattarkhan Street, Tehran

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Iran University Of Medical Sciences

**Full name of responsible person**

Najmossadat Atefi

**Position**

Associate Professor, Dermatologist

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## Person responsible for updating data

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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*