

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 2026

### A comparative study between conventional and liposomal topical hydroquinone 4 % on melasma treatment

#### Protocol summary

##### Summary

Melasma is a common acquired hyperpigmentation seen mainly in women and occurs on the face. This study aims to compare the effects of liposomal and conventional hydroquinone on patients with Melasma. Patients with age over 18 years old are included in the study and asked to fill out written consent forms. Then patients who have exclusion criteria like pregnancy and breastfeeding, drug use, infectious skin diseases, not having regular follow ups and etc will be excluded from study. A double blind clinical trial is conducted among 20 women for 12 weeks. Participants are asked to use liposomal hydroquinone on one side of face and topical hydroquinone on the other side of face once a day and sunblock every 3 hours a day. Skin pigmentation is then measured using MASI (Melasma area severity index) during each visit separately for each side and 1 month after last visit. Then the data obtained from patients file are statistically analyzed using SPSS software, paired samples T test and repeated measured ANOVA.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201405283862N13**

Registration date: **2017-10-09, 1396/07/17**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-10-09, 1396/07/17

##### Registrant information

###### Name

Farahzad Jababri Azad

###### Name of organization / entity

Mashahd University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 1843 6626

###### Email address

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###### Recruitment status

**Recruitment complete**

###### Funding source

Mashhad University of Medical Sciences

###### Expected recruitment start date

2013-12-02, 1392/09/11

###### Expected recruitment end date

2017-09-22, 1396/06/31

###### Actual recruitment start date

empty

###### Actual recruitment end date

empty

###### Trial completion date

empty

###### Scientific title

A comparative study between conventional and liposomal topical hydroquinone 4 % on melasma treatment

###### Public title

Comparison of the effect of conventional and liposomal topical hydroquinone 4 % on melasma treatment

###### Purpose

Treatment

###### Inclusion/Exclusion criteria

Inclusion Criteria: Clinical Melasma; age over 18.

Exclusion criteria: Pregnancy or breastfeeding; Infectious skin diseases; Simultaneous important medical conditions; Drug use (OCP, anticonvulsants, recent hormone therapy and Corticosteroids); Patients who used bleaching drug treatment in the last 4 months; Patients who had laser and IPL operations in the last 6 months;

Patients who did not have follow ups at regular appointed times; In case of side effects.

### Age

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

### Gender

Female

### Phase

N/A

### Groups that have been masked

*No information*

### Sample size

Target sample size: **20**

### Randomization (investigator's opinion)

N/A

### 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 Mashhad University of Medical Sciences

##### Street address

Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah Street

##### City

Mashhad

##### Postal code

##### Approval date

2014-02-08, 1392/11/19

##### Ethics committee reference number

IR.MUMS.REC.1392.806

## Health conditions studied

### 1

#### Description of health condition studied

Melasma

#### ICD-10 code

L81.1

#### ICD-10 code description

Chloasma

## Primary outcomes

### 1

#### Description

disease severity

#### Timepoint

once a month and one month after last visit

#### Method of measurement

Melasma area severity index

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: liposomal hydroquinone %4 was prescribed for one side of face once a day and also use of sunblock every 3 hours daily for 12 weeks.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: conventional topical hydroquinone %4 was prescribed for one side of face once a day and also use of sunblock every 3 hours daily for 12 weeks.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Ghaem Hospital

##### Full name of responsible person

Dr Faeze Golnouri

##### Street address

Ahmad Abad Avenue, Ghaem Hospital

##### City

Mashhad

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice Chancellor for research of Mashhad University of Medical Sciences

##### Full name of responsible person

Dr Mohsen Tafaghodi

##### Street address

Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street

##### City

Mashhad

**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 of Mashhad 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**  
Mashhad University of Medical Sciences  
**Full name of responsible person**  
Dr Faeze Golnouri  
**Position**  
Dermatology Assistant  
**Other areas of specialty/work**  
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## Person responsible for scientific inquiries

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Dr Mahnaz Banihashemi  
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Professor of dermatology

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## Person responsible for updating data

**Contact**  
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Mashhad University of Medical Sciences  
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Akram Momenzadeh  
**Position**  
Bachelor of Biology  
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00  
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src@mums.ac.ir  
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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*