

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

### Effect of hydroquinone 4% topical cream versus glucosamine 2% topical cream on treatment of melasma: a double-blind randomized clinical trial

#### Protocol summary

##### Study aim

To assess the effect of t hydroquinone 4% topical cream versus glucosamine 2% topical cream on treatment of melasma

##### Design

This is a double -blind randomized clinical trial, phase III, in which 24 eligible patients will be randomly assigned to the intervention and control groups

##### Settings and conduct

The eligible patients with melasma referring to the Sina Hospital in Hamadan city during the study period will be enrolled in the trial and will be randomly assigned to the intervention groups through the drawing of lots. This trial will be double -blinded so that neither patients nor the physician examining the patients will be aware of the intervention.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 65 years; Existence of mild melasma symmetrically on both sides of the face;  
Exclusion criteria: Pregnancy; Existence of other skin diseases; History of skin laser-therapy; Using sunscreen; Allergy to hydroquinone or glucosamine

##### Intervention groups

Intervention group 1: Hydroquinone 4% topical cream (manufactured by Behvarzan Pharmaceutical Co.) once every night for 8 weeks plus SFP50 sunscreen (manufactured by Dr. Jila Pharmaceutical Co.) 3 times a day for 8 weeks  
Intervention group 2: Glucosamine 2% topical cream (manufactured by Behvarzan Pharmaceutical Co.) once every night for 8 weeks plus SFP50 sunscreen (manufactured by Dr. Jila Pharmaceutical Co.) 3 times a day for 8 weeks

##### Main outcome variables

Primary outcome: Lesion size

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20120215009014N399**

Registration date: **2021-06-21, 1400/03/31**

Registration timing: **prospective**

Last update: **2021-06-21, 1400/03/31**

Update count: **0**

#### Registration date

2021-06-21, 1400/03/31

#### Registrant information

##### Name

Jalal Poorolajal

##### Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 81 1838 0090

##### Email address

poorolajal@umsha.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2021-07-06, 1400/04/15

#### Expected recruitment end date

2022-03-06, 1400/12/15

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Effect of hydroquinone 4% topical cream versus glucosamine 2% topical cream on treatment of melasma:

a double-blind randomized clinical trial

**Public title**

Effect of hydroquinone 4% topical cream versus glucosamine 2% topical cream on treatment of melasma

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Age of 18 to 65 years; Existence of mild melasma symmetrically on both sides of the face;

**Exclusion criteria:**

Pregnancy; Existence of other skin diseases; History of skin laser-therapy; Using sunscreen; Allergy to hydroquinone or glucosamine

**Age**

From **18 years** old to **65 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Outcome assessor

**Sample size**

Target sample size: **24**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Random assignment of the right and left sides of the patients to the intervention and control groups through the drawing of lots. To do this, we prepare two sheets and write "right" on one sheet and "left" on another. Then, by referring to every patient, one of the sheets will be randomly taken. According to whether the sheet is taken right or left is assigned to the intervention group and the other side to the control group.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The shape of the medications will be perfectly the same. Therefore, patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Thus, the trial will be run as double -blind.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee**

**Name of ethics committee**

Ethics Committee of Hamadan University of Medical Sciences

**Street address**

Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838695

**Approval date**

2021-01-30, 1399/11/11

**Ethics committee reference number**

IR.UMSHA.REC.1399.922

**Health conditions studied****1****Description of health condition studied**

Melasma

**ICD-10 code**

L81.1

**ICD-10 code description**

Chloasma

**Primary outcomes****1****Description**

Lesion size

**Timepoint**

Before the intervention and 2, 4, 6 and 8 weeks after that

**Method of measurement**

By photography

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group 1: Hydroquinone 4% topical cream (manufactured by Behvarzan Pharmaceutical Co.) once every night for 8 weeks plus SFP50 sunscreen (manufactured by Dr. Jila Pharmaceutical Co.) 3 times a day for 8 weeks

**Category**

Treatment - Drugs

**2****Description**

Intervention group 2: Glucosamine 2% topical cream (manufactured by Behvarzan Pharmaceutical Co.) once

every night for 8 weeks plus SFP50 sunscreen  
(manufactured by Dr. Jila Pharmaceutical Co.) 3 times a  
day for 8 weeks

**Category**

Treatment - Drugs

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Sina Hospital in Hamadan city

**Full name of responsible person**

Dr Behnam Moafi

**Street address**

Sina Hospital, Mirzadeh Eshghi Ave.

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838695

**Phone**

+98 81 3827 4184

**Email**

dr.behnammoafi@yahoo.com

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr. Saeid Bashirian

**Street address**

Hamadan University of Medical Sciences, Shahid  
Fahmideh Ave

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838695

**Phone**

+98 81 3838 0717

**Email**

info.research@umsha.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Hamedan 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**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr Behnam Moafi

**Position**

Dermatology Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dermatology

**Street address**

School of Medicine, Hamadan University of Medical  
Sciences, Shahid Fahmideh Ave.

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838695

**Phone**

+98 81 3838 0572

**Email**

dr.behnammoafi@yahoo.com

**Person responsible for scientific  
inquiries**

**Contact**

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr. Pedram Alirezaei

**Position**

Dermatologist

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dermatology

**Street address**

School of Medicine, Hamadan University of Medical  
Sciences, Shahid Fahmideh Ave.

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838695

**Phone**

+98 81 3838 0572

**Email**

drpedramalirezaei@gmail.com

## Person responsible for updating data

poorolajal@umsha.ac.ir

### Contact

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr. Jalal Poorolajal

**Position**

Professor of Epidemiology

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Epidemiology

**Street address**

School of Public Health, Hamadan University of  
Medical Sciences, Shahid Fahmideh Ave

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838695

**Phone**

+98 81 3838 0090

**Email**

## Sharing plan

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

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available