

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

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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
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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

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School of Medicine, Hamadan University of Medical
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**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

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Person responsible for updating data

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Contact

Name of organization / entity

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Full name of responsible person

Dr. Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

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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