

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 2026

### Effect of Phytochemical and skin lightening of herbal formulation of Punica granatum and Crocus sativus versus Azelaic acid cream in patients with post inflammatory hyperpigmentation: a double-blind randomized clinical trial

#### Protocol summary

##### Study aim

To assess the effect of Phytochemical and skin lightening of herbal formulation of Punica granatum and Crocus sativus versus Azelaic acid cream in patients with post inflammatory hyperpigmentation

##### Design

This is a double-blind randomized clinical trial with control group, phase III, in which right and left side of the eligible patients will be randomly assigned through the drawing of lots to the intervention and control groups

##### Settings and conduct

This study will be performed in the Sina Hospital in Hamadan city on 40 eligible patients. The patients will be randomly assigned to the intervention and control groups through the drawing of lots. This trial will be double-blinded.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 18 to 60 years; Post-inflammatory hyperpigmentation. Exclusion criteria: Pregnancy or breastfeeding; Having a skin disease; Taking retinoid drugs in the last three months; Taking contraceptive or anti-inflammatory or immunosuppressive drugs.

##### Intervention groups

Intervention group: Herbal cream containing pomegranate and saffron extract on the left side of the face twice a day for 12 weeks Control group: Cream Azelaic acid 20% on the right side of the face twice a day for 12 weeks

##### Main outcome variables

Hyperpigmentation; side effects

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20120215009014N450**

Registration date: **2022-12-19, 1401/09/28**

Registration timing: **prospective**

Last update: **2022-12-19, 1401/09/28**

Update count: **0**

##### Registration date

2022-12-19, 1401/09/28

##### 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

2023-02-20, 1401/12/01

##### Expected recruitment end date

2023-07-22, 1402/04/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of Phytochemical and skin lightening of herbal formulation of Punica granatum and Crocus sativus versus Azelaic acid cream in patients with post inflammatory hyperpigmentation: a double-blind randomized clinical trial

#### Public title

Effect of Phytochemical and skin lightening of herbal formulation of Punica granatum and Crocus sativus versus Azelaic acid cream in patients with post inflammatory hyperpigmentation

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Age 18 to 60 years Post-inflammatory hyperpigmentation

##### Exclusion criteria:

Pregnancy or breastfeeding Having a skin disease Taking retinoid drugs in the last three months Taking contraceptive or anti-inflammatory or immunosuppressive drugs

#### Age

From **18 years** old to **60 years** old

#### Gender

Both

#### Phase

3

#### Groups that have been masked

- Participant
- Outcome assessor

#### Sample size

Target sample size: **40**

#### 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 and placebos 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

2022-12-03, 1401/09/12

#### Ethics committee reference number

IR.UMSHA.REC.1401.735

## Health conditions studied

### 1

#### Description of health condition studied

Postinflammatory hyperpigmentation

#### ICD-10 code

L81.0

#### ICD-10 code description

Postinflammatory hyperpigmentation

## Primary outcomes

### 1

#### Description

Improvement of hyperpigmentation signs

#### Timepoint

Before treatment and 4, 8 and 12 weeks after treatment

#### Method of measurement

Using post acne hyperpigmentation index (PAHPI)

## Secondary outcomes

### 1

#### Description

Side effects (including dryness, redness or peeling of the skin at the site of application of the cream)

#### Timepoint

At weeks 4 and 12

#### Method of measurement

By taking a history

## Intervention groups

## 1

### Description

Intervention group: Herbal cream containing pomegranate and saffron extract on the left side of the face twice a day for 12 weeks

### Category

Treatment - Drugs

## 2

### Description

Control group: Cream Azelaic acid 20% on the right side of the face twice a day for 12 weeks

### Category

Treatment - Drugs

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Sina Hospital in Hamadan city

#### Full name of responsible person

Fatemeh Hamidbeigi

#### Street address

Sina Hospital, Mirzadeh Eshghi Ave.

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6517838695

#### Phone

+98 81 3827 4184

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fh.moghadam1999@gmail.com

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Hamedan University of Medical Sciences

#### Full name of responsible person

Dr. Reza Shokoohi

#### Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

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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

Fatemeh Hamidbeigi

#### Position

Student of Pharmacology

#### Latest degree

Medical doctor

#### Other areas of specialty/work

Dermatology

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

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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. Dara Dastan

#### Position

Pharmacologist

#### Latest degree

Ph.D.

#### Other areas of specialty/work

Medical Pharmacy

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**Person responsible for updating data****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****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