

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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)

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+98 81 1838 0090

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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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Reza Shokoohi

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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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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr. Dara Dastan

Position

Pharmacologist

Latest degree

Ph.D.

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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

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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