Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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Name of organization / entity
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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

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Province

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Postal code

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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
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Sponsors / Funding sources

1

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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
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Person responsible for updating data

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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