

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 2026

### Evaluating the effect of Irsa(Iris Germanica L.) topical product on melasma

#### Protocol summary

##### Study aim

Determining and comparing the size and color of skin lesions before the intervention and 4, 8, 12, 16 weeks after the intervention between the intervention group and the control group

##### Design

A clinical trial with a control group, with parallel groups, three blind strains, randomized phase 3 on 66 patients. The rand function of Excel software was used for randomization.

##### Settings and conduct

The location of the project is the Skin Research Center. After the melasma is confirmed by the dermatologist, Irsa product or hydroquinone cream is randomly applied in the envelope and how to use it.(Apply at night and wash off in the morning and use sunscreen during the day) A code is assigned to each sealed envelope by the software, and one of these codes is randomly assigned to each participant by the software, and the corresponding envelope containing the medicine is delivered to the patient. The person who registers the codes in the software is different from the person who delivers the envelope to the patient.

##### Participants/Inclusion and exclusion criteria

Women aged 18-60 years Having clear lesions of melasma with expert approval Main conditions of non-entry: Pregnancy or breastfeeding Local or systemic treatment of melasma in the last 4 weeks Use of hormonal drugs (OCP and corticosteroids).

##### Intervention groups

Intervention group: Applying a thin layer of Irsa topical product to the affected area every night. Control group: Applying a thin layer of Hydroquinon ointment to the lesion site every night.

##### Main outcome variables

Reducing the size and reducing the color of melasma lesions

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230729058956N1**

Registration date: **2023-10-24, 1402/08/02**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-10-24, 1402/08/02**

Update count: **0**

##### Registration date

2023-10-24, 1402/08/02

##### Registrant information

##### Name

Maryam Iranzadasl

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8869 3565

##### Email address

m.iranzad@shahed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-09-23, 1402/07/01

##### Expected recruitment end date

2024-09-22, 1403/07/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluating the effect of Irsa(Iris Germanica L.) topical product on melasma

#### Public title

effect of Irsa(Iris Germanica L.) topical product on melasma

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Women aged 18-60 years Having clear lesions of melasma with expert approval

##### Exclusion criteria:

Pregnancy or breastfeeding Local or systemic treatment of melasma in the last 4 weeks Use of hormonal drugs (OCP and corticosteroids).

#### Age

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

#### Gender

Female

#### Phase

3

#### Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

#### Sample size

Target sample size: **66**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Randomization method: Randomization is simple and each participant is randomly assigned to the treatment of the main intervention group or the treatment of the control group. The randomization unit is individual. Randomization tool: Excel software is used to generate random numbers and sealed envelopes. A code is assigned to each sealed envelope by the software, and one of these codes is randomly assigned to each participant by the software, and the corresponding envelope containing the medicine is delivered to the patient. The person who registers the codes in the software is different from the person who delivers the envelope to the patient. How to make a random sequence using a table of random numbers.

#### Blinding (investigator's opinion)

Triple blinded

#### Blinding description

The samples of the two intervention and control groups are not aware of the active substance inside the tubes due to the similarity of the tubes and the substance inside, and the pharmacist gives a code to each of them that only he knows, and the prescribing physician in the research plan is also not aware of the contents. And finally, after the end of the study, the appropriate medicine will be prescribed to the samples in accordance with the ethical principles of the research. Therefore, because the samples, the researchers and the analyst do not know, it will be blinded on three sides.

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Shahid University

##### Street address

Persian Gulf Freeway

##### City

Tehran

##### Province

Tehran

##### Postal code

3319118651

#### Approval date

2023-07-17, 1402/04/26

#### Ethics committee reference number

IR.SHAHED.REC.1402.053

## Health conditions studied

### 1

#### Description of health condition studied

Melasma

#### ICD-10 code

L81.1

#### ICD-10 code description

Chloasma

## Primary outcomes

### 1

#### Description

Color index of melasma lesions

#### Timepoint

Measurement of the color index of melasma lesions at the beginning of the study (before the start of the intervention) and 4.8.12.16 weeks after the start of the use of Irsa topical product.

#### Method of measurement

Comparing the amount of skin darkening compared to healthy skin (natural skin color 0, brief darkness 1, mild darkness 2, moderate darkness 3, severe darkness 4) by observation, photography and megometer device

## Secondary outcomes

## 1

### **Description**

The extent of melasma lesions

### **Timepoint**

Measuring the extent of melasma lesions at the beginning of the study (before the start of the intervention) and 4, 8, 12, 16 weeks after the start of using the Irsa topical product.

### **Method of measurement**

Calculating the area of the lesion using MASI score and VISIOFACE

## **Intervention groups**

## 1

### **Description**

"Intervention group": includes people who receive Irsa cream. For 12 weeks, a thin layer of cream is applied on the spots in the morning and at night, and sunscreen is used during the day. Method of preparation of the cream: extraction is done from the rhizomes of the plant by the maceration method and using ethanol. After 72 hours, the resulting mixture is filtered and concentrated by rotary. The resulting liquid is completely dried and kept in a refrigerator at a temperature of 4 degrees Celsius until consumption. The extract is standardized in terms of total phenol and flavonoids. The cream is prepared with 5% of Irsa extract using cold cream as a cream base. The prepared cream is stored in 50 gram containers at refrigerator temperature. After using the cream, patients are examined every 4 weeks to 12 weeks and 4 weeks after the end of the treatment period, and the size of the spots is determined with the visio face device and the MASI SCORE index, and the color of the spots is measured with the German MPA CK megometer. The light of the room, the place of taking the photo, the place of measuring the color change of the spots, the angle of taking the photo are the same. In each visit, patients are evaluated in terms of drug consumption, improvement of lesions (size and color of lesions), disease progression, and occurrence of complications. "Control group": includes people who receive hydroquinone cream. The creams in both groups are filled in unlabeled tubes.

### **Category**

Treatment - Drugs

## 2

### **Description**

"Control group": includes people who receive hydroquinone cream. The creams are filled in unlabeled tubes. For 12 weeks, patients apply a thin layer of cream on the spots in the morning and at night, and use sunscreen during the day.

### **Category**

Treatment - Drugs

## **Recruitment centers**

## 1

### **Recruitment center**

#### **Name of recruitment center**

Dermatology and Leprosy Research Center, University of Tehran

#### **Full name of responsible person**

Masoomeh Akhoondi Ghahroodi

#### **Street address**

No.415.Naderi ,Street Taleghani Street

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masoomehakhoondi3@gmail.com

## **Sponsors / Funding sources**

## 1

### **Sponsor**

#### **Name of organization / entity**

Shahed University

#### **Full name of responsible person**

Maryam Iranzad Asl

#### **Street address**

Persian Gulf Express way

#### **City**

Tehran

#### **Province**

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3319118651

#### **Phone**

+98 21 5121 4055

#### **Email**

m.iranzad@shahed.ac.ir

#### **Grant name**

#### **Grant code / Reference number**

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

Yes

#### **Title of funding source**

Shahed University

#### **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**

Shahed University

**Full name of responsible person**

masoomeh akhoondi ghahroodi

**Position**

student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Traditional Medicine

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No. 14, Ashrafi Esfahani Street, Koche 21

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Shahed University

**Full name of responsible person**

Maryam Iranzad Asl

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Traditional Medicine

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Shahed University

**Full name of responsible person**

Maryam Iranzadasl

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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## Sharing plan

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

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

All data is potentially shareable after de-identifying individuals

**When the data will become available and for how long**

The access period starts 6 months after the results are published

**To whom data/document is available**

Researchers working in academic, scientific and research institutions

**Under which criteria data/document could be used**

It is allowed to use the data for the purpose of meta-analyses and by preserving all the rights of the creators of this data.

**From where data/document is obtainable**

By referring to the scientific officer of the research Ms. Dr. Maryam Iranzad Asl at the email address m\_iranzadasl@yahoo.com and at the address of Shahed University, Fars Gulf Highway, Tehran, Tehran Province, Iran. zip code 3319118651. contact number 00982151214055.

**What processes are involved for a request to access data/document**

The applicant's request will be sent to the mentioned e-mail containing the applicant's profile, the purpose of receiving the data, and the details of the desired data, and it will be checked for compliance of the conditions and data requested with the publication conditions within a maximum of one month, and an appropriate response

will be sent.

## Comments