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 ofHydroquinon 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
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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 theintervention) and 4،8،12،16 weaks after the start of using the Irsa topica lproduct.
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
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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
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

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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