Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the effectiveness of cream containing Rhaphanus sativus seed extract in treatment of women with facial melasma - A triple blind clinical trial

Protocol summary

Study aim

Determining the effectiveness of cream containing Raphanus sativus seed extract on women with melasma

Design

Thriple-blind clinical trial, with case and control groups, with parallel groups, randomized by block random method using R software version 4.1.1, phase 3, on 25 patients as splite face

Settings and conduct

25 patients with bilateral melasma randomly use a cream containing Raphanus sativus seed extract on one side of the face and a placebo cream on the other side. Visit of a dermatologist at the Dermatology and Leprosy Research Center, Before starting treatment, at 6 weeks and 12 weeks of study and calculate and insert the mMASI for each side of the patient's face. Data analysis by a statistician. Dermatologist and statistician won't know which side of the face was treated by drug.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Clinical diagnosis of melasma by a dermatologist; Female gender; Age of over 18 years; Bilateral facial melasma. Criteria for not entering: Pregnancy and breastfeeding; Use any topical treatment for melasma within 2 months before the start of the study; Taking oral contraceptives and hormonal drugs during the 4 weeks before the study; Use of drugs that increase sensitivity to sunlight; Such as doxycycline, minocycline, tetracycline, ciprofloxacin, hydrochlorothiazide and sulfonamides; The presence of scars, tattoos, excessive hair, or any other condition that makes the test site less likely to be evaluated.

Intervention groups

After 25 patients with bilateral melasma are included in the study, each of them randomly use the Raphanus sativus seed cream on one side of their face and the placebo cream on the other side, a fingertip each time, twice a day.

Main outcome variables

Modified Melasma Area and Severity Index; Possible skin side effects of drugs; self-assessment; Physician consent; Recurrence rate; Visual Analogue Scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220223054106N1**
Registration date: **2022-06-18, 1401/03/28**
Registration timing: **prospective**

Last update: **2022-06-18, 1401/03/28**
Update count: **0**

Registration date

2022-06-18, 1401/03/28

Registrant information

Name

Fatemeh Sharifi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-23, 1401/05/01

Expected recruitment end date

2023-07-23, 1402/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effectiveness of cream containing Rhaphanus sativus seed extract in treatment of women with facial melasma - A triple blind clinical trial

Public title

Evaluation of the effectiveness of Raphanus sativus in melasma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Clinical diagnosis of melasma by a dermatologist (at the Center for Dermatology and Leprosy Research) Female gender Age of over 18 years Bilateral facial melasma

Exclusion criteria:

Pregnancy and breastfeeding Use of any topical treatment for melasma during 2 months before the start of the study Taking oral contraceptives and hormonal drugs for 4 weeks before the study Use of drugs that increase sensitivity to sunlight; Such as doxycycline, minocycline, tetracycline, ciprofloxacin, hydrochlorothiazide and sulfonamides The presence of scars, tattoos, excessive hair, or any other condition that makes the test site less likely to be evaluated

Age

From **18 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **25**

More than 1 sample in each individual

Number of samples in each individual: **2**

Each patient uses the medication on one side of their face and the placebo on the other side of their face.

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization, Individual randomization, using statistical software R version 4.1.1. 25 Raphanus sativus seed extract creams and 25 placebo creams will be prepared by a traditional pharmacist. In each group of the prepared creams, the number 1 to 25 will be pasted on can of each of the creams. One of the phrases "right" or "left" will be randomly selected by block randomization method using R software version 4.1.1 and written next to the number of cans of Raphanus sativus seed extract creams. Matching the cream numbers to the right or left phrases will be kept confidential by the pharmacist until the end of the data analysis. Next to the placebo box number, a phrase opposite to what was placed in the same box number will be written. Each patient will be given two cans of cream with the same numbers. The right phrase is written on one of them and the left phrase is written on the other. (One of the cans will be Raphanus sativus seed extract cream and the other will be a placebo cream.)

Blinding (investigator's opinion)

Triple blinded

Blinding description

Participant: Each patient will be given two cans of cream with the same numbers, that the phrase "right" is written on one and the phrase "left" on the other randomly. (One of the cans will be Raphanus sativus seed extract cream and the other will be a placebo cream.) Patients will use each of the creams according to the phrase written on the can, on the same side, without knowing which of the creams is the drug cream and which is the placebo cream. Matching the cream numbers to the right or left phrases will be kept confidential by the pharmacist until the end of the data analysis. Outcome Evaluator: Patients before the start of treatment, in the 6th and 12th week of the study will be evaluated by a dermatologist and the number of mMASI as an indicator of severity and level of melasma involvement for each species (regardless of which species Is treated with drugs and which species is treated with placebo) will be calculated and written. Data Analyzer: At the end of the study, data collected from each patient will be presented to a statistician for review and analysis; And without knowing which item was treated with the drug and which was treated with the placebo, he determines the effectiveness or ineffectiveness of the cream used on each cheek in treating patient's melasma. Finally, the statistics obtained will be matched by the researcher with the list held by the pharmacist.

Placebo

Used

Assignment

Parallel

Other design features

This study is designed by splite face method; This means that each patient will randomly take the medication on one side of their face and the placebo on the other side of their face.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Ahmadieh Health Center, Sarparast St., Taleghani St.

City

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Province

Tehran

Postal code

1416663361

Approval date

2022-02-12, 1400/11/23

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1400.1289

Health conditions studied

1

Description of health condition studied

Melasma

ICD-10 code

L81.0

ICD-10 code description

Primary outcomes

1

Description

mMASI = Modified Melasma Area and Severity Index. This index is generally calculated based on the following formula: MMASI = 0.3 A (f) D (f) + 0.3 A (Lm) D (Lm) + 0.3 A (Rm) D (Rm + 0.1 A (C) D (C) . Area = A, Darkness= D, lesions in the Forehead = F, Right malar = Rm, Left malar = Lm and Chin = C. Our MMASI is evaluated separately in each half of the face, calculated with the following formula: Modified MASI score = (f) 0.15A (D + H) + (m) 0.3A (D + H) + (c) 0.05A (D + H) The calculated number varies between zero and 24 depending on the severity of the lesion, the higher the score indicates the severity of the lesion. The Area (A) is determined between zero and 6; So that: 0 = 0% - 1 = 1 to 9% - 2 = 10 to 29% - 3 = 30 to 49% - 4 = 50 to 69% - 5 = 70 to 89% - 6 = 90 to 100% Darkness (D), used to determine the maxameter at the Center for Dermatology and Leprosy Research, is rated between zero and 4; In this way: 0 = normal; 1 = very low opacity; 2 = low opacity; 3 = significant opacity; 4 = severe opacity. Homogeneity (H) is also graded between zero and 4: 0 = non-homogeneity; 1 = low homogeneity; 2 = moderate homogeneity; 3 = high homogeneity.

Timepoint

At the beginning of the study (before the intervention) and 6 weeks, 12 weeks and 16 weeks after the intervention.

Method of measurement

Photograph with visio face camera to evaluate the darkness of facial skin and mexameter to examine Modified Melasma Area and Severity Index

Secondary outcomes

1

Description

Visual Analogue Scale

Timepoint

Before the intervention, the 6th and 12th week after the intervention

Method of measurement

Scaled questionnaire from zero to 10

2

Description

Self-assessment

Timepoint

6th and 12th week after the intervention

Method of measurement

Five-point Likert Scale

3

Description

Possible skin complications

Timepoint

6th and 12th week after intervention

Method of measurement

Common Terminology Criteria for Adverse Events (CTCAE) version 5.0

Intervention groups

1

Description

Intervention group: Patients will use on one side of their face a cream containing Raphanus sativus seed extract based on propylene glycol and with a concentration of 25%, twice a day (morning and night), one fingertip for 12 weeks.

Category

Treatment - Drugs

2

Description

Control group: On the other side of face, patients will use the placebo cream twice a day (morning and night) at the rate of one fingertip for 12 weeks. Placebo cream will be based on propylene glycol with a concentration of 25% and a few drops of eatable color will be added to it. Also, a few drops of Raphanus sativus seed extract will be sprayed on the back of the door of cream so that the patient can smell the Raphanus sativus when he opens the cream.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahmadiyeh Traditional Medicine Health Center

Full name of responsible person

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2

Recruitment center

Name of recruitment center
Center for research and training in skin disease and leprosy

Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

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Full name of responsible person
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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
Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Fatemeh Sharifi

Position
Phd student in Persian Madicine

Latest degree
Medical doctor

Other areas of specialty/work
Traditional Medicine

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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