Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

Efficacy of oily oral product of Carthamus tinctorius in comparison with placebo on the treatment of melasma: a randomized controlled clinical trial

Protocol summary

Study aim
Determining the effect of safflower seed oily food product in the treatment of melasma

Design
A controlled randomized clinical trial, double blinded, phase 3 on 40 patients, using Random Allocation Software for randomization.

Settings and conduct
Samples include the patients with melasma who refer to the Shahid Faghih Dermatology Clinic. In order to blind the investigator and patients, medications are named as A for capsule of safflower seeds oil and B for placebo.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Diagnosis of melasma by a dermatologist; The patient is bound to cooperate for regular use of the studied drug and refer at the appointed time; Having informed and written consent to participate in the study; Satisfaction with not using out-of-protocol therapies. Exclusion criteria: ;Pregnant and lactating women; History of hypersensitivity reaction to safflower seeds; Patient dissatisfaction to continue the project for any reason; Individuals with diabetes; Taking skin lightening medications in the last two weeks; Taking hormonal contraceptives and other medications that cause melasma; Taking anticoagulants (aspirin, Plavix, warfarin); Individuals with coagulation diseases.

Intervention groups
Intervention group: Patients in the intervention group will receive 8 grams of oily capsule containing safflower seed oil (manufactured by Barij Company) orally, daily. Also, patients in this group will use hydroquinone 4% cream (made by Pars Daroo company) every night for two hours before going to bed. Placebo group: Patients in the placebo group will receive 8 grams of paraffin-containing capsules (made by Barij Company) orally, daily. Also, these patients will use 4% hydroquinone cream made by Pars Daroo company every night for two hours before going to bed.

Main outcome variables
The amount of melanin pigment in the site of melasma

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150825023753N15**
Registration date: **2020-10-18, 1399/07/27**
Registration timing: **registered_while_recruiting**

Last update: **2020-10-18, 1399/07/27**
Update count: **0**

Registration date
2020-10-18, 1399/07/27

Registrant information

Name
Mohammad Mahdi Parvizi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 71 3212 5592

Email address
parvizim@sums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-10-11, 1399/07/20

Expected recruitment end date
2021-03-20, 1399/12/30

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Efficacy of oily oral product of Carthamus tinctorius in comparison with placebo on the treatment of melasma: a randomized controlled clinical trial

Public title
Efficacy of oral safflower oil in treatment of melasma
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosis of melasma by a dermatologist The patient is bound to cooperate for regular use of the studied drug and refer at the appointed time Having informed and written consent to participate in the study Satisfaction with not using out-of-protocol therapies
Exclusion criteria:
Pregnant and lactating women Individuals with other organ disorders (cancers, liver, kidney) History of hypersensitivity reaction to safflower seeds 39/5000Patient dissatisfaction to continue the project for any reason Individuals with diabetes Taking skin lightening medications in the last two weeks Taking hormonal contraceptives and other medications that cause melasma Taking anticoagulants (aspirin, Plavix, warfarin) Individuals with coagulation diseases History of hypersensitivity to safflower seeds
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Random allocation software Ink is used to create blocks. Then, patients based on their allocated numbers are placed in groups A or B considering the designed table.
Blinding (investigator's opinion)
Double blinded
Blinding description
In order to blind the investigator, medications were named A (oily capsule of safflower) and B (Placebo). The patients were not aware of which drug they received. The groups were also coded A and B to the statistical analyzer
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences
Street address
Shiraz University of Medical Sciences, Zand blv., Shiraz, Fars, Iran
City
Shiraz
Province
Fars
Postal code
14336 - 71348
Approval date
2020-04-08, 1399/01/20
Ethics committee reference number
IR.SUMS.REC.1399.126

Health conditions studied

1

Description of health condition studied
Melasma
ICD-10 code
L81.1
ICD-10 code description
Chloasma

Primary outcomes

1

Description
The rate of melasma discoloration
Timepoint
Measurements are taken at the start of the study, one month and two months after the start of the study
Method of measurement
Using Visioface 1000D and The Melasma Area and Severity Index (MASI)

Secondary outcomes

1

Description

Quality of life of patients with melasma

Timepoint

This variable is measured at the beginning of the study and two months later.

Method of measurement

The Melasma Quality of Life scale (MELASQOL)

Intervention groups

1

Description

Intervention group: Patients in the intervention group will receive 8 grams of oily capsule containing safflower seed oil (manufactured by Barij Company) orally, daily. Also, patients in this group will use hydroquinone 4% cream (made by Pars Daroo company) every night for two hours before going to bed.

Category

Treatment - Drugs

2

Description

Control group: Patients in the placebo group will receive 8 grams of paraffin-containing capsules (made by Barij Company) orally, daily. Also, these patients will use 4% hydroquinone cream made by Pars Daroo company every night for two hours before going to bed.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Faghihi Dermatology Clinic

Full name of responsible person

Dr. Nasrin Saki

Street address

Shahid Faghihi Hospital, Zand Avenue

City

Shiraz

Province

Fars

Postal code

71348466114

Phone

+98 71 3212 5592

Email

nasrinsa85@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Younes Ghsemi

Street address

7th floor,Vice Chancellor of Research, Shiraz University of Medical Sciences, Zand Blvd., Shiraz, Iran

City

Shiraz

Province

Fars

Postal code

7134814336

Phone

+98 71 3230 5410

Email

vcrdep@sums.ac.ir

Grant name

98-01-65-21047

Grant code / Reference number

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

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Mahdi Parvizi

Position

Assisstant professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

Street address

Zand Ave, Shahid Faghihi Hospital,

City

Shiraz

Province

Fars

Postal code

7134846114

Phone

+98 71 3212 5592

Email

mmparvizi@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr. Mohammad Mahdi Parvizi
Position
Assisstant professor
Latest degree
Ph.D.
Other areas of specialty/work
Traditional Medicine
Street address
Zand Ave, Shahid Faghihi Hospital,
City
Shiraz
Province
Fars
Postal code
7134846114
Phone
+98 71 3212 5592
Email
mmparvizi@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr. Mohammad Mahdi Parvizi
Position
Assisstant professor
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Email
mmparvizi@gmail.com

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
Demographic data and the result of the clinical trial
When the data will become available and for how long
One year later
To whom data/document is available
Researchers
Under which criteria data/document could be used
After publication of the extracted article of the clinical trial
From where data/document is obtainable
Sending Email to the researchers
What processes are involved for a request to access data/document
Sending the request via the email
Comments