# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

18 Sep 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**
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**Phone**
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**Email**
mmparvizi@gmail.com

## Person responsible for updating data

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Dr. Mohammad Mahdi Parvizi

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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**
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**