# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Jun 2026

## Evaluation of oral product of Carthamus tinctorius effect on cardiovascular risk factors among metabolic syndrome patients

## Protocol summary

**Study aim**

Determination of the effect of edible safflower seeds on cardiovascular risk factors in patients with metabolic syndrome and introducing this product as a useful food product in the field of treatment in the case of proven efficacy

**Design**

A Clinical trials, block method randomized, two parallel groups of 45 which double-blinded will begin in June 2018 and over after 10 months

**Settings and conduct**

The study will be conducted in Shiraz. Intervention group patients will receive 8 safflower capsules, every 6 hours a day. Alongside, placebo group patients will receive same number of paraffin capsules with same frequency. Intervention will be continued for 12 consecutive weeks. Participants will be followed up monthly by telephone or re-visiting. Patients and physician are blinded.

**Participants/Inclusion and exclusion criteria**

Inclusion criteria: Informed and written consent to participate in the study Body mass index (BMI) above 27 Having three signs of the five features of metabolic syndrome based on NCEP-ATPIII definitions Exclusion criteria: Use of out-of-protocol treatments Use of drugs associated with the treatment of metabolic syndrome in the past month Sensitivity to safflower seeds Kidney, liver, cancer, thyroid and/or coagulation disease Pregnancy and/or lactation Tobacco use, alcohol and/or substance abuse Taking anti-platelet and anticoagulant drugs (such as aspirin, clopidogrel, warfarin, etc.)

**Intervention groups**

The intervention and placebo group will receive safflower and paraffin capsules, respectively, for 12 weeks.

**Main outcome variables**

Changes in serum total cholesterol, LDL, HDL, TG, FBS, insulin levels, leptin levels, adiponectin levels, AST, ALT, systolic and diastolic blood pressure, WHR and BMI, frequency of bowel habit and stool consistency

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20180515039673N1**
Registration date: **2018-08-01, 1397/05/10**
Registration timing: **registered_while_recruiting**

Last update: **2018-08-01, 1397/05/10**
Update count: **0**

**Registration date**

2018-08-01, 1397/05/10

**Registrant information**

**Name**

Maede Ruyvaran

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

**Phone**

+98 71 3234 5145

**Email address**

ruyvaran@sums.ac.ir

**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2018-06-10, 1397/03/20

**Expected recruitment end date**

2019-04-09, 1398/01/20

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Evaluation of oral product of Carthamus tinctorius effect on cardiovascular risk factors among metabolic syndrome patients

**Public title**
Effect of safflower oral product in treatment of metabolic syndrome
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Informed and written consent for participation in the study / Body mass index (BMI) above 27 / Having three signs of the five characteristics of the metabolic syndrome based on the definitions of NCEP-ATPIII
**Exclusion criteria:**
Use of extra- protocol treatments / Use of drugs associated with treatment of metabolic syndrome in the past month / Safflower allergy /positive history of kidney, liver, cancer, thyroid and/or coagulation disease / pregnancy and/or lactation / smoking, alcohol and/or substance abuse / Taking anti-platelet and anticoagulant drugs (such as Aspirin, Clopidogrel, Warfarin, etc.)
**Age**
From **30 years** old to **65 years** old
**Gender**
Both

**Phase**
3
**Groups that have been masked**

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

**Sample size**
Target sample size: **90**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
Randomization method is block type along with using a random number table.
**Blinding (investigator's opinion)**
Double blinded
**Blinding description**
Patients, the drug delivery officer, physician and the statistical analyst of the results, will be blind, and only the drug manufacturer can decode based on the original form of randomization.
**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**
Medical school, Zand street
**City**
Shiraz
**Province**
Fars
**Postal code**
7134845794
**Approval date**
2018-04-16, 1397/01/27
**Ethics committee reference number**
IR.SUMS.MED.REC.1397.058

## Health conditions studied

### 1

**Description of health condition studied**
Metabolic syndrome includes pre-diabetes, dyslipidemia, overweight and obesity and hypertension
**ICD-10 code**
E88.81
**ICD-10 code description**
Metabolic syndrome

## Primary outcomes

### 1

**Description**
Percentage of people with hypertension
**Timepoint**
Measuring hypertension at the beginning of the study (before the intervention) and 1, 2 and 3 months after the onset of intervention.
**Method of measurement**
Automated sphygmomanometer

## Secondary outcomes

### 1

**Description**
Composition of body components
**Timepoint**
Measurement at the beginning of the study (before the intervention) and 12 weeks after intervention
**Method of measurement**
Medical body Composition Analyzer

## Intervention groups

**1**

**Description**
Intervention group: One gram capsules made by Barij-Essence Pharmaceutical Company contains safflower oil, which 8 of them will be given daily with 6-hour intervals for next 12 weeks.

**Category**
Treatment - Drugs

**2**

**Description**
Control group: One gram capsules made by Barij-Essence Pharmaceutical Company contains liquid paraffin, which 8 of them will be given daily with 6-hour intervals for next 12 weeks.

**Category**
Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**
Motahari clinic

**Full name of responsible person**
Maede Ruyvaran

**Street address**
Namazi squere

**City**
Shiraz

**Province**
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0000000

**Phone**
+98 71 3612 1000

**Email**
Ruyvaran@sums.ac.ir

**2**

**Recruitment center**

**Name of recruitment center**
Shahid Faghihi clinic

**Full name of responsible person**
Maede Ruyvaran

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Zand street

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## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**
Shiraz University of Medical Sciences

**Full name of responsible person**
Seyed Basir Hashemi

**Street address**
Central building, Zand street

**City**
Shiraz

**Province**
Fars

**Postal code**
1433671348

**Phone**
+98 71 3230 5410

**Email**
nimroozi@sums.ac.ir

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**
No

**Title of funding source**
Nothing

**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**
Maede ruyvaran

**Position**
Resident

**Latest degree**
Medical doctor

**Other areas of specialty/work**
Traditional Medicine

**Street address**
Traditional medicine department, Medical school, Zand street

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**Province**
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## Person responsible for scientific inquiries

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**Other areas of specialty/work**
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## Person responsible for updating data

**Contact**
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Maede ruyvaran
**Position**
Ph.d candidate
**Latest degree**
Medical doctor
**Other areas of specialty/work**
Traditional Medicine
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Traditional medicine department, Medical school, Zand street
**City**
Shiraz
**Province**
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**Postal code**
7134845794
**Phone**
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**Email**
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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**
Yes - There is 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
**Title and more details about the data/document**
IPD collected for the primary outcome measure such as physical examination changes and laboratory findings only.
**When the data will become available and for how long**
starting 12 months after publication.
**To whom data/document is available**
People working in academic institutions
**Under which criteria data/document could be used**
There is not any decision yet.
**From where data/document is obtainable**
Contact with main researcher
**What processes are involved for a request to access data/document**
After correspondence with the researcher, within the framework of the declarations and in the shortest possible time
**Comments**