

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### Comparison of effects of canola oil and soybean oil on biochemical markers in overweight and obese patients with type 2 diabetes mellitus

#### Protocol summary

##### Summary

Patients will randomly be assigned to one of three groups: 1. receiving 30 grams canola oil for 2 months; 2. receiving 30 grams soybean oil for 2 months; 3. control group (consume their usual dietary fat). A 24-hour questionnaire in the first day, end of first month and end of second month will be completed for each patient. 10 ml blood will be obtained from every patient at beginning and at the end of second month and serum will be separated for analysis of following parameters: FBS, HbA1c, Triglyceride, Cholesterol, HDL, LDL, VLDL, CBC, ESR, and CRP.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2012062510110N1**  
Registration date: **2012-07-23, 1391/05/02**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2012-07-23, 1391/05/02

##### Registrant information

##### Name

Mahmoud Ali Kaykhaei

##### Name of organization / entity

Zahedan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 54 1341 1296

##### Email address

keikhaeim@zaums.ac.ir

##### Recruitment status

##### Recruitment complete

##### Funding source

Zahedan University of Medical Sciences

##### Expected recruitment start date

2012-07-15, 1391/04/25

##### Expected recruitment end date

2013-01-14, 1391/10/25

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of effects of canola oil and soybean oil on biochemical markers in overweight and obese patients with type 2 diabetes mellitus

##### Public title

Investigation of effects of canola oil and soy bean oil in diabetes mellitus

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion: Overweight or obese type 2 diabetes patients; 30 to 65 years old. Exclusion: Hyperglycemias not due to diabetes; liver, thyroid, kidney diseases; treatment with insulin; acute infections; anti lipid drugs; beta blockers; BMI ≤ 24.9, BMI ≥ 40.

##### Age

From **30 years** old to **65 years** old

##### Gender

Both

##### Phase

N/A

##### Groups that have been masked

*No information*

##### Sample size

Target sample size: **90**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

Mercury sphygmomanometer

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Zahedan University of Medical Sciences

##### Street address

Dr. Hesabi Sq, Pardis Building

##### City

Zahedan

##### Postal code

#### Approval date

2011-10-25, 1390/08/03

#### Ethics committee reference number

90-1477

## Health conditions studied

### 1

#### Description of health condition studied

type 2 diabetes mellitus

#### ICD-10 code

E11

#### ICD-10 code description

Non-insulin-dependent diabetes mellitus

### 2

#### Description of health condition studied

Obesity

#### ICD-10 code

E66.0

#### ICD-10 code description

Obesity due to excess calories

## Primary outcomes

### 1

#### Description

Blood Pressure

#### Timepoint

Beginning and 2 months after intervention

#### Method of measurement

### 2

#### Description

Body Mass Index

#### Timepoint

Beginning and 2 months after intervention

#### Method of measurement

Measurement of Height and Weight and calculation by formula: Weight/Height<sup>2</sup>

### 3

#### Description

Fasting Glucose

#### Timepoint

Beginning and 2 months after intervention

#### Method of measurement

Available commercial kit

### 4

#### Description

HbA1c

#### Timepoint

Beginning and 2 months after intervention

#### Method of measurement

Available commercial kit

### 5

#### Description

Serum Lipids( TG,Chol, LDL, HDL, VLDL)

#### Timepoint

Beginning and 2 months after intervention

#### Method of measurement

Available commercial kit

### 6

#### Description

Complete Blood Count (CBC)

#### Timepoint

Beginning and 2 months after intervention

#### Method of measurement

Cell Counter

### 7

#### Description

Erythrocyte Sedimentation Rate (ESR)

#### Timepoint

Beginning and 2 months after intervention

#### Method of measurement

ESR Pipette

### 8

#### Description

CRP

#### Timepoint

Beginning and 2 months after intervention

#### Method of measurement

Available commercial kit

## Secondary outcomes

1

### Description

Inflammatory and Antioxidant markers

### Timepoint

Beginning and 2 months after intervention

### Method of measurement

Available commercial kits

## Intervention groups

1

### Description

Intervention 1 canola oil 30 grams daily for 2 months

### Category

Treatment - Other

2

### Description

Intervention 2 soybean oil 30 grams daily for 2 months

### Category

Treatment - Other

3

### Description

Control group Continue their previous diet for 2 months

### Category

Treatment - Other

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Diabetes Clinic

#### Full name of responsible person

Dr. Mansour Shahraki

#### Street address

Aliasghar Hospital, Azadi Ave.

#### City

Zahedan

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Zahedan University of Medical Sciences

#### Full name of responsible person

Ms. Soodabeh Hashemzahi

#### Street address

Deputy of Research, Pardis

### City

Zahedan

### Grant name

90

### Grant code / Reference number

10506

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

Yes

### Title of funding source

Zahedan University of Medical Sciences

### Proportion provided by this source

100

### Public or private sector

*empty*

### Domestic or foreign origin

*empty*

### Category of foreign source of funding

*empty*

### Country of origin

### Type of organization providing the funding

*empty*

## Person responsible for general inquiries

### Contact

#### Name of organization / entity

Zahedan University of Medical Sciences

#### Full name of responsible person

Dr. Mansour Shahraki

#### Position

PhD in Nutrition/ Educator

#### Other areas of specialty/work

#### Street address

Dept. of Nutrition, Medical School

#### City

Zahedan

#### Postal code

#### Phone

#### Fax

#### Email

shahrakimansour@yahoo.com

#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Zahedan University of Medical Sciences

#### Full name of responsible person

Dr. Mansour Shahraki

#### Position

PhD in Nutrition/ Educator

#### Other areas of specialty/work

#### Street address

Dept. of Nutrition, School of Medicine

#### City

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**Email**

shahrakimansour@yahoo.com

**Web page address****Email**

mazyar44@yahoo.com

**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Zahedan University of Medical Sciences

**Full name of responsible person**

Dr. Mahmoud Ali Kaykhaei

**Position**

Endocrinologist/ Educator

**Other areas of specialty/work****Street address**

Dept. of Medicine, Ali ebb abitaleb Hospital

**City**

Zahedan

**Postal code****Phone****Fax****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*