

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/Height²

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

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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