

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

Comparison of the effect of consuming olive oil and sunflower oil as the substitute for a portion of daily dietary fat on fasting and postprandial blood glucose and lipid profile in type 2 diabetic female patients

Protocol summary

Summary

This study is conducted to compare the effect of consuming olive oil and sunflower oil as the substitute for a portion of daily dietary fat on fasting and postprandial blood glucose and lipid profile in type 2 diabetic female patients. This randomized crossover clinical trial is conducted on 20 postmenopausal women less than 60 years old with type 2 diabetes. Their average daily intake of hydrogenated oil is measured by completing a 3 day 24-hour dietary recall. Then, the patients randomly are assigned into 2 groups, consuming either olive oil or sunflower oil (instead of hydrogenated oil) for 3 weeks. After a washout period of 3 weeks, subjects are switched to the other oil for the next 3 weeks. Anthropometric measurements and biochemical tests are done at the beginning of the study, and at the end of the weeks 3, 6, and 9. Postprandial biochemical tests are performed after the consumption of the patient's usual breakfast. Every 3 week, a 1day 24-hour dietary recall is also obtained.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138808202697N1**

Registration date: **2010-01-05, 1388/10/15**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2010-01-05, 1388/10/15

Registrant information

Name

Salomeh Armin

Name of organization / entity

Shaheed Beheshti University of Medical Sciences -
Faculty of Nutrition Sciences and Food Technology

Country

Iran (Islamic Republic of)

Phone

+98 21 2236 0658

Email address

s.armin@nnftri.ac.ir

Recruitment status

Recruitment complete

Funding source

Shaheed Beheshti University of Medical Sciences and
Health Services -School of Nutrition Sciences and Food
Technology - Department of Human Nutrition

Expected recruitment start date

2009-12-07, 1388/09/16

Expected recruitment end date

2010-02-08, 1388/11/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of consuming olive oil and
sunflower oil as the substitute for a portion of daily
dietary fat on fasting and postprandial blood glucose and
lipid profile in type 2 diabetic female patients

Public title

Comparison of the effect of consuming olive oil and
sunflower oil on blood glucose and lipid profile in type 2
diabetic female patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria -Type II diabetes (FBS>126mg/dl) - Menopause women. Less than 60 years old -Not taking insulin and any drug that affects lipids metabolism (lipid-lowering drugs, multivitamins, hormones and beta-blockers) -No heart, liver, kidney diseases, no hypothyroidism or hyperthyroidism -Consumption of hydrogenated vegetable oil and no consumption of olive oil, sunflower oil and corn oil during the three weeks before starting the study -No abusing of smoke, alcohol or drugs Exclusion criteria -Not following the recommended diet changes -More or less than 5 percent changes in the body weight during one month - Occurrence of gastrointestinal, liver or ischemic heart diseases -Any changes in taking medicines or starting to take insulin -Taking any drug that affects lipids metabolism (lipid-lowering drugs, multivitamins, hormones and beta-blockers) during study -Changes in physical activity

Age

To 60 years old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 20

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

National Nutrition and Food Technology Research Institute

Street address

No 46, Arghavan-e-gharbi St., Farahzadi Blv., Shahrak-e-Ghods.

City

Tehran

Postal code

19395-4741

Approval date

2009-11-29, 1388/09/08

Ethics committee reference number

033A01

Health conditions studied

1

Description of health condition studied

Diabetes mellitus

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description

Fasting Blood Sugar (FBS)

Timepoint

At the beginning of the study, and at the end of the weeks 3, 6, and 9.

Method of measurement

FBS, PPBS measurement

Secondary outcomes

1

Description

Blood Lipids

Timepoint

At the beginning of the study, and at the end of the weeks 3, 6, and 9.

Method of measurement

Fasting and Postprandial Blood Triglyceride, Total Cholesterol, LDL-C, HDL-C, TC/HDL-C, LDL-C/HDL-C, TG/HDL-C levels measurement

Intervention groups

1

Description

Olive oil - 40% of total dietary fat intake - for 3 weeks

Category

Treatment - Other

2

Description

Sunflower oil - 40% of total dietary fat intake - for 3 weeks

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Iran University of Medical Sciences, Endocrine and Metabolism Institute

Full name of responsible person

Dr. Abbas Rashad

Street address

3rd floor, Next to Firuzgar Hospital, Shahid Valadi St., Vali-e-Asr Sq., Vali-e-Asr St. .

City

Tehran

Shahrak-e-Ghods.

City

Tehran

Postal code

193954741

Phone

+98 21 2236 0658

Fax

+98 21 2237 6470

Email

s.armin@nnftri.ac.ir

Web page address

www.nnftri.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shaheed Beheshti University of Medical Sciences - Faculty of Nutrition Sciences and Food Technology

Full name of responsible person

Dr. Farideh Tahbaz

Street address

No 46, Arghavan-e-gharbi St., Farahzadi Blv., Shahrak-e-Ghods.

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shaheed Beheshti University of Medical Sciences -Faculty of Nutrition Sciences and Food Technology

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

Shaheed Beheshti University of Medical Sciences - Faculty of Nutrition Sciences and Food Technology

Full name of responsible person

Saloomeh Armin

Position

M.Sc. in Nutrition Sciences

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

No 46, Arghavan-e-gharbi St., Farahzadi Blv.,

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shaheed Beheshti University of Medical Sciences - Faculty of Nutrition Sciences and Food Technology

Full name of responsible person

Dr. Forough Azam Taleban

Position

Professor, Department of Human Nutrition

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

No 46, Arghavan-e-gharbi St., Farahzadi Blv., Shahrak-e-Ghods.

City

Tehran

Postal code

19395-4741

Phone

+98 21 2235 7484

Fax

+98 21 2236 0660

Email

f.taleban@nnftri.ac.ir

Web page address

www.nnftri.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Shaheed Beheshti University of Medical Sciences , National Nutrition and Food Technology Research In

Full name of responsible person

Zinat Kamali

Position

M.Sc. in Nutrition Sciences

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

No 46, Arghavan-e-gharbi St., Farahzadi Blv., Shahrak-e-Ghods.

City

Tehran

Postal code

193954741

Phone

+98 21 2236 0658

Fax

+98 21 2237 6470

Email

z.kamali@nnftri.ac.ir

Web page address

www.nnftri.ac.ir

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