

# 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

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##### 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. .

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## 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**

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**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**

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

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**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*