

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 2026

### Comparing the effect of canola oil and olive oil on blood lipids, oxidative stress, insulin resistance, blood pressure and inflammation in women with type 2 diabetes

#### Protocol summary

##### Summary

The main objective of the study: Comparing the effect of canola oil and olive oil on blood lipids, oxidative stress, insulin resistance, blood pressure and inflammation on the population of women with type 2 diabetes. Study design: Non-randomized, not blinded, without a placebo control, single center. Study population: Women with type 2 diabetes. Conditions for Inclusion criteria: "female gender; at least 6 months history of diabetes; routine consumption of sunflower oil". Conditions for exclusion: "needing blood fat-lowering drugs; using insulin; Existence of thyroid disorders; kidney and liver disease; cardiovascular disease; participating in other studies in 6 months before; history of allergies; consumption of corticosteroids, immunosuppressive NSAIDs, cyclosporine and warfarin; Smoking; alcohol use; Having LDL over 160 and Having TG over 400". Sample size: 75 people. Intervention: They are randomly divided into three groups by balanced block. In group, 30 grams of olive or canola or sunflower oil daily is given for 8 weeks. Time intervention: 8 weeks. Primary outcome: Lipid profile. Secondary outcome: Oxidative stress, resistance insulin, blood pressure, inflammation.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015062722818N1**  
Registration date: **2016-02-12, 1394/11/23**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-02-12, 1394/11/23

#### Registrant information

##### Name

Masume Atefi

##### Name of organization / entity

Shiraz University of Medical Science

##### Country

Iran (Islamic Republic of)

##### Phone

+98 25 3292 9575

##### Email address

stud0386015376@sums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Vice Chancellery for Research of Shiraz University of Medical Sciences

#### Expected recruitment start date

2015-07-23, 1394/05/01

#### Expected recruitment end date

2015-11-22, 1394/09/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Comparing the effect of canola oil and olive oil on blood lipids, oxidative stress, insulin resistance, blood pressure and inflammation in women with type 2 diabetes

#### Public title

Comparison of olive oil and canola oil on the lipid profile in patients with type 2 diabetes

#### Purpose

Other

#### Inclusion/Exclusion criteria

Inclusion criteria: female gender; at least 6 months history of diabetes; routine consumption of sunflower oil. Exclusion criteria: needing blood fat-lowering drugs; using insulin; Existence of thyroid disorders; kidney and liver disease; cardiovascular disease; participating in other studies in 6 months before; history of allergies; consumption of corticosteroids, immunosuppressive; NSAIDs; cyclosporine; warfarin; Smoking; alcohol use; Having LDL over 160 and Having TG over 400.

**Age**

No age limit

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: 75

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not 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**

Central Building of Shiraz University of Medical Sciences, Zand Street, Shiraz

**City**

Shiraz

**Postal code****Approval date**

2015-06-05, 1394/03/15

**Ethics committee reference number**

IR.SUMS.REC.1394.27

**Health conditions studied****1****Description of health condition studied**

Type 2 diabetes

**ICD-10 code**

E00,E90

**ICD-10 code description**

Nutritional, endocrine and metabolic diseases

**Primary outcomes****1****Description**

Lipid profile

**Timepoint**

Before and after the intervention

**Method of measurement**

Blood test

**Secondary outcomes****1****Description**

Oxidative stress, insulin resistance, blood pressure and inflammation

**Timepoint**

Before and after the intervention.

**Method of measurement**

Blood test

**Intervention groups****1****Description**

Intervention group 1: 30 grams daily olive oil from Famila brand for 8 weeks

**Category**

Treatment - Other

**2****Description**

Intervention group 2: 30 grams daily canola oil from Ladan brand for 8 weeks

**Category**

Other

**3****Description**

Control group: 30 grams daily sunflower oil from Ladan Brand for 8 weeks

**Category**

Other

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Motahari Clinic

**Full name of responsible person**

Dr. Gholamreza Pishdad

**Street address**

Motahari Clinic, Namazi Square, Shiraz

**City**

Shiraz

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Vice Chancellery for Research of Shiraz University of Medical Sciences

**Full name of responsible person**

Dr. Mohammad Hadi Imanieh

**Street address**

Central Building of Shiraz University of Medical Sciences, Zand Street, Shiraz

**City**

Shiraz

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Vice Chancellery for Research of Shiraz 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**

Shiraz University of Medical Sciences

**Full name of responsible person**

Masume Atefi

**Position**

M.Sc student in major of Health Sciences in Nutrition

**Other areas of specialty/work**

**Street address**

No. 15, 15th Alley, Mohammad Amin Boulevard, Qom

**City**

Qom

**Postal code**

**Phone**

+98 25 3292 9575

**Fax**

**Email**

atefi.masume@yahoo.com

**Web page address**

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Masume Atefi

**Position**

M.Sc student in major of Health Sciences in Nutrition

**Other areas of specialty/work**

**Street address**

No. 15, 15th Alley, Mohammad Amin Boulevard, Qom

**City**

qom

**Postal code**

**Phone**

+98 25 3292 9575

**Fax**

**Email**

atefi.masume@yahoo.com

**Web page address**

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Masume Atefi

**Position**

M.Sc student in major of Health Sciences in Nutrition

**Other areas of specialty/work**

**Street address**

No. 15, 15th Alley, Mohammad Amin Boulevard, Qom

**City**

Qom

**Postal code**

**Phone**

+98 25 3292 9575

**Fax**

**Email**

atefi.masume@yahoo.com

**Web page address**

## 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*