

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 May 2026

### Effects of walnut oil on lipid profiles in hyperlipidemic type 2 diabetic patients

#### Protocol summary

##### Summary

Our study has been designed with the aim of investigating the effects of walnut oil on lipid profiles of hyperlipidemic type 2 diabetic patients. In a double-blind, randomized placebo-controlled study, 90 hyperlipidemic type 2 diabetic patients aged between 18-75 referred to Shiraz Healthy Heart Home have been selected according to the inclusion criteria, including plasma TG level more 150 mg/dL or total cholesterol level more 200 mg/dL or LDL between 130-200 or HDL less 50 in female and less 40 in male, and the use of maximum 2 oral diabetes medications. The exclusion criteria have been a history of chronic or metabolic diseases, and the use of insulin and antihyperlipidemic agents. These patients are assigned to receive 15cc Persian walnut (*Juglans regia* L.) oil or placebo, per day, for 60 days. In order to obtain the values for lipid profiles, "Total cholesterol, TG, HDL, LDL" all of the participants are measured in 2 episodes (before starting the intervention and at the end of intervention).

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014030611375N2**

Registration date: **2014-04-09, 1393/01/20**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2014-04-09, 1393/01/20

##### Registrant information

###### Name

pouya farhadi

###### Name of organization / entity

Shiraz University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 71 1625 4206

###### Email address

farhadip@sums.ac.ir

###### Recruitment status

**Recruitment complete**

###### Funding source

Cardiovascular Research center, Shiraz University of Medical Sciences

###### Expected recruitment start date

2013-10-10, 1392/07/18

###### Expected recruitment end date

2014-01-10, 1392/10/20

###### Actual recruitment start date

empty

###### Actual recruitment end date

empty

###### Trial completion date

empty

###### Scientific title

Effects of walnut oil on lipid profiles in hyperlipidemic type 2 diabetic patients

###### Public title

Effects of walnut oil on lipid profiles in hyperlipidemic type 2 diabetic patients

###### Purpose

Treatment

###### Inclusion/Exclusion criteria

Inclusion Criteria: Patients with diagnosed type2 diabetes for at least 2 years and also with either plasma TG level more 150 mg/dL or total cholesterol level more 200 mg/dL or LDL between 130-200 or HDL less 50 in female and less 40 in male; Patients who received maximum 2 oral diabetes medications. Exclusion Criteria: Patients who have a history of chronic or metabolic diseases, or

regularly use medication (Fibrate and HMG-COA Reductase inhibitor) or supplements known to affect blood lipids; Patients who have to receive antihyperlipidemic agents for example CAD patients; Patients who were currently received insulin therapy.

#### **Age**

From **20 years** old to **75 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**

Used

#### **Assignment**

Parallel

#### **Other design features**

### **Secondary Ids**

empty

### **Ethics committees**

#### **1**

##### **Ethics committee**

###### **Name of ethics committee**

Shiraz University of Medical Sciences

###### **Street address**

Shiraz university of medical sciences Building - 7th floor - Zand Ave.

###### **City**

Shiraz

###### **Postal code**

##### **Approval date**

2013-08-13, 1392/05/22

##### **Ethics committee reference number**

CT-P-92-5376

### **Health conditions studied**

#### **1**

##### **Description of health condition studied**

Hyperlipidemia

##### **ICD-10 code**

E78

##### **ICD-10 code description**

Disorders of lipoprotein metabolism and other lipidaemias

### **Primary outcomes**

#### **1**

##### **Description**

Serum Triglyceride

##### **Timepoint**

Before and 3 months after intervention

##### **Method of measurement**

Biochemical measurements on blood sample (GPA-PAP technique)

#### **2**

##### **Description**

Low-density lipoprotein (LDL)

##### **Timepoint**

Before and 3 months after intervention

##### **Method of measurement**

Biochemical measurements on blood sample (GPA-PAP technique)

#### **3**

##### **Description**

High-density lipoprotein (HDL)

##### **Timepoint**

Before and 3 months after intervention

##### **Method of measurement**

Biochemical measurements on blood sample (dextran magnesium sulfate)

#### **4**

##### **Description**

Total cholesterol

##### **Timepoint**

Before and 3 months after intervention

##### **Method of measurement**

Biochemical measurements on blood sample (GPA-PAP technique)

### **Secondary outcomes**

#### **1**

##### **Description**

Body Mass Index

##### **Timepoint**

Before and 2 months after intervention

##### **Method of measurement**

By BMI Formula

#### **2**

##### **Description**

Systolic Blood Pressure

##### **Timepoint**

Before and 3 months after intervention

##### **Method of measurement**

Mercury sphygmomanometer

### 3

#### **Description**

Diastol Blood Pressure

#### **Timepoint**

Before and 3 months after intervention

#### **Method of measurement**

Mercury sphygmomanometer

### **Intervention groups**

#### 1

#### **Description**

Intervention group will be administered with 15cc Persian walnut (*Juglans regia* L.) oil, per day, for 90 days.

#### **Category**

Treatment - Drugs

#### 2

#### **Description**

Control group will be received placebo (distilled water capsule) per day, for 90 days.

#### **Category**

Placebo

### **Recruitment centers**

#### 1

#### **Recruitment center**

##### **Name of recruitment center**

Cardiovascular Research Center of Shiraz University of Medical Sciences

##### **Full name of responsible person**

Dr. Abbas Mosleh

##### **Street address**

Cardiovascular Research Center, Shahid Faghihi Hospital, Zand Blvd

##### **City**

Shiraz

### **Sponsors / Funding sources**

#### 1

#### **Sponsor**

##### **Name of organization / entity**

Shiraz University of Medical Sciences

##### **Full name of responsible person**

Mrs Hoghooghi

##### **Street address**

Cardiovascular Research center, Shahid Faghihi Hospital, Zand Blvd

##### **City**

Shiraz

#### **Grant name**

#### **Grant code / Reference number**

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

Yes

#### **Title of funding source**

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**

Dr. pouya Farhadi

##### **Position**

General Physician

##### **Other areas of specialty/work**

##### **Street address**

Cardiovascular Research Center, Shahid Faghihi Hospital, Zand ave.

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farhadip@sums.ac.ir

##### **Web page address**

### **Person responsible for scientific inquiries**

#### **Contact**

##### **Name of organization / entity**

Cardiovascular Research Center of Shiraz

##### **Full name of responsible person**

Dr. Mohammad Javad Zibaeenejhad

##### **Position**

Fellowship of Interventional Cardiology

##### **Other areas of specialty/work**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Dr.Pouya Farhadi

**Position**

General Physician

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

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Medical Sciences, Zand ave.

**City**

Shiraz

**Postal code****Phone**

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**Fax****Email**

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**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*