

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

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farhadip@sums.ac.ir

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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

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Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr.Pouya Farhadi

Position

General Physician

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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