

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effects of olive and grape seed oil consumption on metabolic responses and lipid profiles in hyperlipidemic patients

Protocol summary

Summary

This study was designed to compare the effects of olive and grape seed oil on serum lipids and blood pressure in hyperlipidemic patients referring to Obesity Center of Shahid Sadoughi University of medical sciences Specialty and Subspecialty Baghaeipour Clinic in 2014. In this parallel clinical trial, 60 hyperlipidemic patients aged 30-60 year without cardiac, renal or hepatic disease will be recruited. After obtaining informed consent, subjects will be assigned to 3 groups using the table of random numbers: 1) Consuming 20 ml/day refined olive oil (2 teaspoonful in the morning and 2 in the afternoon) 2) Consuming 20 ml/day refined grape seed oil 3) The control group will receive no oil. The intervention period is six weeks. All participants should take cardiac Step I diet. At baseline refined oil (that are colorless and odorless) will be poured in coded graded containers by a person who is not participate in the process of the study. Blood pressure is measured at baseline and after 6 weeks using a standard mercurial column sphygmomanometer (Model FC-110Deluxe, Focal Corporation, Japan). Total cholesterol, high density lipoprotein, triglyceride and fasting serum glucose will also be measured at baseline and after 6 weeks by enzymatic methods using certified commercial kits (Pars Azmon, Iran). Low density lipoprotein level will be calculated by the Friedewalds formula.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014070218329N1**
Registration date: **2015-02-13, 1393/11/24**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-02-13, 1393/11/24

Registrant information

Name

Fatemeh Kaseb

Name of organization / entity

Diabetes Research Center, Shahid Sadoughi University of medical sciences, Yazd, Iran

Country

Iran (Islamic Republic of)

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+98 35 3821 5197

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Diabetes Research Center, Shahid Sadoughi University of medical sciences, Yazd, Iran

Expected recruitment start date

2014-03-22, 1393/01/02

Expected recruitment end date

2014-07-27, 1393/05/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of olive and grape seed oil consumption on metabolic responses and lipid profiles in hyperlipidemic patients

Public title

Effect of olive and grape seed oil on lipid profile

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: At least one of lipid profile indicators should be elevated (TC \geq 200, HDL \leq 40, LDL \geq 130, TG \geq 150), 30-60 years of age, lack of cardiac, renal or hepatic disease and not using antioxidant supplements, no pregnancy or lactation. Exclusion criteria: Change in physical activity, diet or medications; using less than 80% of the given oil.

Age

From **30 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Because of using refined oil participants and researchers who conduct the study will not know which oil will be taken by them.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahid Sadoughi University of medical sciences, Yazd, Iran

Street address

Talare Honar Alley, Shahid Sadoughi Blvd.

City

Yazd

Postal code

Approval date

2013-08-17, 1392/05/26

Ethics committee reference number

17/1/102034/پ

Health conditions studied

1

Description of health condition studied

Hyperlipidemia

ICD-10 code

E78.5

ICD-10 code description

Hyperlipidaemia, unspecified

Primary outcomes

1

Description

Blood pressure

Timepoint

At the start of intervention and 6 weeks after intervention

Method of measurement

Mercurial column sphygmomanometer

2

Description

Total cholesterol

Timepoint

At the start of intervention and 6 weeks after intervention

Method of measurement

Enzymatic

3

Description

High density lipoprotein (HDL)

Timepoint

At the start of intervention and 6 weeks after intervention

Method of measurement

Enzymatic

4

Description

Triglyceride

Timepoint

At the start of intervention and 6 weeks after intervention

Method of measurement

Enzymatic

5

Description

Low density lipoprotein (LDL)

Timepoint

At the start of intervention and 6 weeks after intervention

Method of measurement

Friedewalds formula

6

Description

Very low density lipoprotein (VLDL)

Timepoint

At the start of intervention and 6 weeks after intervention

Method of measurement

Enzymatic

7

Description

weight

Timepoint

At the start of intervention and 6 weeks after intervention

Method of measurement

Seca scale

8

Description

Serum glucose

Timepoint

At the start of intervention and 6 weeks after intervention

Method of measurement

Enzymatic

9

Description

Height

Timepoint

At the start of intervention and 6 weeks after intervention

Method of measurement

Seca scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention 1: 20 mL refined grape seed oil/day (XXX company, Italy) + Having Step I diet (for 6 weeks)

Category

Lifestyle

2

Description

Intervention 2: 20 mL refined olive oil/day (Kokab Olive Oil Company, Qazvin, Iran) + Having Step I diet (for 6 weeks)

Category

Lifestyle

3

Description

Intervention 3: control: Receiving no oil and consuming + Having step I diet (for 6 weeks)

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Obesity Center, Specialty and Subspecialty Baghaeipour Clinic, Shahid Sadoughi University of medical

Full name of responsible person

Mohammad Hossein Baradaranfar

Street address

Talare Honar Alley, Shahid Sadoughi Blvd.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Shahid Sadoughi University of medical sciences, Yazd, Iran

Full name of responsible person

Nasim Namiranian

Street address

Talare Honar Alley, Shahid Sadoughi Blvd.

City

Yazd

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research of Shahid Sadoughi University of medical sciences, Yazd, Iran

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

Shahid Sadoughi University of medical sciences, Yazd, Iran

Full name of responsible person

Akram Naghdipour Biregani

Position

MSc in Health Sciences in Nutrition

Other areas of specialty/work

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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