

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparing of the effects of olive oil and ghee consumption on plasma lipids and lipoproteins, adiponectin, and insulin in healthy adults

Protocol summary

Study aim

To compare the effects of a diet rich in olive oil and a diet rich in ghee on plasma total, LDL, and HDL cholesterol, apo B, TG as well as insulin, adiponectin and liver enzyme in healthy adults.

Design

A randomized, crossover intervention, not blinded, on 30 subjects. A table of random numbers will be used for randomization.

Settings and conduct

The study will involve a 2-week run-in period using reference oil (olive oil) at the end of which baseline measurements will be made. Subjects will then be randomized to one of the two treatments for a period of 4 weeks with two 2-week washout periods in between during which reference oil will be consumed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: I. Adult male and non-menopausal female aged 20-60 year Exclusion criteria: I. History of type 2 diabetes or atherosclerotic disease II. Abnormal liver function test (ALT and AST > 45 U/L) III. Abnormal kidney function test (creatinine > 1.4 mg/dL) IV. On lipid lowering medication V. Pregnancy and breast feeding VI. Female on oral contraceptive unless they have no intention to change during the study.

Intervention groups

Diet with ghee Diet with refined olive oil

Main outcome variables

Plasma LDL-Cholesterol and Apo B

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160702028742N9**

Registration date: **2021-01-05, 1399/10/16**

Registration timing: **registered_while_recruiting**

Last update: **2021-01-05, 1399/10/16**

Update count: **0**

Registration date

2021-01-05, 1399/10/16

Registrant information

Name

Javad Nasrollahzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2236 0656

Email address

jnasrolah@razi.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-02, 1399/10/13

Expected recruitment end date

2021-02-20, 1399/12/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing of the effects of olive oil and ghee consumption on plasma lipids and lipoproteins, adiponectin, and insulin in healthy adults

Public title

Effects of ghee consumption on plasma lipids in healthy adults

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

I. Adult male and non-menopausal female aged 20-60 year

Exclusion criteria:

I. History of type 2 diabetes II. History of coronary heart disease III. Abnormal liver function test (ALT and AST > 45 U/L) III. Abnormal kidney function test (creatinine > 1.4 mg/dL) IV. On lipid lowering medication V. Pregnancy and breast feeding VI. Female on oral contraceptive unless they have no intention to change during the study

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization method is performed using computer randomization software. For this purpose, in order to randomize whether the consumption of ghee by each person will be first or the second treatment, each person's number will be entered in Excel software and then they are randomized using the RAND function. The first 15 participants will begin study by consuming ghee and the next 15 will begin by consuming the olive oil.

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 Ethic Committee

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No. 7, West Arghavan Ave., Farahzadi Blvd., Qods Town,

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Postal code

1981619573

Approval date

2020-12-01, 1399/09/11

Ethics committee reference number

IR.SBMU.nnftri.Rec.1399.053

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

healthy subjects

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Plasma LDL-cholesterol

Timepoint

Measurements at baseline (before the start of the intervention) and 4 weeks after the start

Method of measurement

Spectrophotometry

2**Description**

Plasma apo B levels

Timepoint

Measurements at baseline (before the start of the intervention) and 4 weeks after the start

Method of measurement

Spectrophotometry

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

Plasma TG

Timepoint

Measurements at baseline and 4 weeks after each intervention

Method of measurement

Spectrophotometry

2**Description**

Plasma ALT

Timepoint

Measurements at baseline and 4 weeks after each intervention

Method of measurement

Spectrophotometry

3**Description**

Plasma Insulin levels

Timepoint

Measurements at baseline and 4 weeks after each intervention

Method of measurement

ELISA

4

Description

Plasma Adiponectin levels

Timepoint

Measurements at baseline and 4 weeks after each intervention

Method of measurement

ELISA

Intervention groups

1

Description

Intervention group: Consume ghee in the diet for 4 weeks. The approximate amount of oil allowed for each person to prepare each of the two meals of lunch and dinner is determined and they are asked that the amount of oil needed to cook food in each of the two meals of lunch and dinner is specified in the amount. People are also advised to consume low-fat animal sources (dairy and meat products).

Category

Lifestyle

2

Description

Control group: Consumption of olive oil in the diet. The approximate amount of oil allowed for each person to prepare each of the two meals of lunch and dinner is determined and they are asked that the amount of oil needed to cook food in each of the two meals of lunch and dinner is specified in the amount. People are also advised to consume low-fat animal sources (dairy and meat products).

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinic of Nutrition and Diet therapy

Full name of responsible person

Susan Mohammadi

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No. 7, West Arghavan Ave., Farahzadi Blvd., Qods Town,

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

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No. 7, West Arghavan Ave., Farahzadi Blvd., Qods Town,

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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

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Javand Nasrollahzadeh

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

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Full name of responsible person

Javad Nasrollahzadeh

Position

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available