

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Comparison of effect of refined olive oil with canola oil consumption on plasma lipids and inflammatory cytokines secretion of whole blood culture in patients referred for coronary angiography

Protocol summary

Study aim

Comparison of effects of refined olive oil or canola oil consumption on plasma lipids and inflammatory cytokines secretion of whole blood culture in patients referred for coronary angiography

Design

A single center, randomized, not blinded, controlled clinical trial with a parallel group design of 40 participants

Settings and conduct

40 patients with at least one cardiovascular risk factor, referred for angiography in Rajaei hospital, will be randomized into two groups, refined olive oil (25 mL refined olive oil per day) or canola oil (25 mL canola oil) for 6 weeks. Plasma concentration of lipoproteins and lipoprotein phospholipase A2, and IL-6 and MCP-1 concentration in cultured whole blood are measured.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: 1) Existence of at least one of the major cardiovascular risk factors 2) Willingness to participate in the study 3) Aged 20-75 years 4) No continuous consumption of any anti-inflammatory and antioxidant supplement such as omega-3, vitamin E, vitamin C and Selenium in last month Exclusion Criteria: 1) Unwillingness to cooperation 2) Advanced hepatic or renal disease 3) Existence of gastrointestinal complications such as diarrhea

Intervention groups

1) Refined olive oil (intervention) 2) Canola oil (control)

Main outcome variables

lipoprotein phospholipase A2 (Lp-PLA2)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160702028742N5**

Registration date: **2019-04-19, 1398/01/30**

Registration timing: **retrospective**

Last update: **2021-01-06, 1399/10/17**

Update count: **1**

Registration date

2019-04-19, 1398/01/30

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

2019-01-01, 1397/10/11

Expected recruitment end date

2019-04-19, 1398/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of effect of refined olive oil with canola oil consumption on plasma lipids and inflammatory cytokines secretion of whole blood culture in patients

referred for coronary angiography

Public title

Comparison of effects of refined olive oil and canola in patients referred for coronary angiography

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Existence of at least one of the major cardiovascular risk factors Willingness to participate in the study No consumption of any anti-inflammatory or antioxidant supplement such as omega-3, vitamin E, vitamin C and Selenium in last month

Exclusion criteria:

Unwillingness to continue Any changes in disease treatment plan such as changes in medical treatment or surgery Existence of gastrointestinal complications such as diarrhea

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: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization method (the easiest method of randomization) using a random numbers table Random numbers table is a list of numbers, composed of the digits 0-9. Numbers in the list are arranged randomly, means that each number has no predictable relationship to the numbers that preceded it or to the numbers that followed it. At first, each member of study population (patients) has been assigned a number. Then, as regard to required sample size, it is randomly started from a point, moved systematically based on previous decision to the right, left, up or down, and the next number is selected. Based on previous decision, odd and even numbers are placed in the control and intervention groups, respectively. The random number allocation was concealed from the researcher and participants.

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 Shahid Beheshti University of Medical Sciences

Street address

No. 46, West Arghavan Ave., Farahzadi Blvd., Qods Town

City

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Province

Tehran

Postal code

1981619573

Approval date

2018-03-13, 1396/12/22

Ethics committee reference number

IR.SBMU.NNFTRI.REC.1396.203

Health conditions studied

1

Description of health condition studied

Coronary Artery Disease

ICD-10 code

I25.1

ICD-10 code description

Atherosclerotic heart disease of native coronary artery

Primary outcomes

1

Description

lipoprotein-associated phospholipase A2 (Lp-PLA2)

Timepoint

Baseline and the end of the study

Method of measurement

ELISA

Secondary outcomes

1

Description

Plasma Lipoproteins

Timepoint

Baseline and the end of the study

Method of measurement

colorimetry

2

Description

Interleukin-6 (IL-6) & Monocyte Chemoattractant Protein-1 (MCP-1) in cultured whole blood

Timepoint

Baseline and the end of the study
Method of measurement
ELISA

Intervention groups

1

Description

Intervention group: Daily consumption of 25 mL of pure canola oil as cold with meals for 6 weeks

Category

Lifestyle

2

Description

Intervention group: Daily consumption of 25 mL of refined olive oil as cold with meals for 6 weeks

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Rajaei Cardiovascular, Medical & Research Center

Full name of responsible person

Dr Ali Zahedmehr

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Niyayesh Conjunction, Valiasr Street, Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

Dr Esmat Naseri

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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

Nafiseh Khandouzi

Position

Ph.D. Student in Nutrition Sciences

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

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Position

Assistant Professor

Latest degree

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Other areas of specialty/work

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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

No - There is not 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

Trial results

Please tick if results have been published

Yes

Summary result posting date

2021-01-06, 1399/10/17

Table of baseline comparison

Participant flow diagram

Table of variable outcomes' results

Table of adverse events

First publication date

empty

Abstract of published paper