Clinical Trial Protocol
Iranian Registry of Clinical Trials

23 Oct 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 Rajaee 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)

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+98 21 2236 0656

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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
Tehran
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 Rajaee Cardiovascular, Medical & Research Center

Full name of responsible person

Dr Ali Zahedmehr

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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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No. 46, Hafezi St, Farahzadi Blvd, Qods Town, Tehran

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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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Assistant Professor

Latest degree

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Other areas of specialty/work

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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