

# 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

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 Rajaei Cardiovascular, Medical & Research Center

##### Full name of responsible person

Dr Ali Zahedmehr

##### Street address

Niyayesh Conjunction, Valiasr Street, Tehran

##### City

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##### Postal code

1995614331

##### Phone

+98 21 23921

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arashzahedmehr@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Dr Esmat Naseri

##### Street address

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

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jnasrollahzadeh@gmail.com

##### 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

#### Contact

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Dr Javad Nasrollahzadeh

##### Position

Assistant Professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

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## Person responsible for updating data

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**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