Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of blended canola and Pistacia Atlantica seed oil compared with blended canola and corn oil with and without synthetic antioxidant TBHQ on serum oxidant and antioxidant status markers in patients with metabolic syndrome

Protocol summary

Study aim
To investigate the effect of canola-Pistacia Atlantica seeds oil (a blend of canola and Pistacia Atlantica seed oils compared with canola–corn oil with TBHQ and canola–corn oil without TBHQ on serum oxidant and antioxidant status markers in patients with metabolic syndrome.

Design
Three way randomized cross-over clinical trial

Settings and conduct
This study will be conducted at the school of Public health. all three oils will be provided in the same packages labeled by a person not aware of the study objectives. Participants and personnel will be blinded to the intervention oil.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Males and females aged 20-50 years and with at least three of 5 metabolic syndrome conditions. Exclusion criteria: history of cardiovascular diseases, diabetes, cancer, liver, kidney, gastrointestinal disease, changing blood glucose and lipid profile control medications in previous 3 months, taking corticosteroids, androgens, phenytoin, erythromycin, hemostatic regulators (other than Asprin), and gastrointestinal medication in last 30 days, alcohol consumption, pregnancy, giving birth in last 12 months, smoking, omega-3 supplement use >1 g/day, severe weight change in previous 3 months, not willing to enter or follow the study protocol

Intervention groups
Each intervention period (phase) will last 8 weeks. The participants will receive canola-Pistacia Atlantica seed oil, canola–corn oil (with TBHQ), and canola–corn oil (without TBHQ) in each intervention period. Intervention periods will be separated with 4 weeks of washout periods (sunflower oil will be provided).

Main outcome variables
Serum total antioxidant capacity, Total oxidant capacity, malondialdehyde, myeloperoxidase , superoxide dismutase , catalase , glutathione peroxidase, glutathione reductase, and nitric oxide levels

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130223012571N8**
Registration date: **2022-03-04, 1400/12/13**
Registration timing: **prospective**

Last update: **2022-03-04, 1400/12/13**
Update count: **0**

Registration date
2022-03-04, 1400/12/13

Registrant information

Name
Amin Salehi-Abargouei

Name of organization / entity
Shahid Sadoughi University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date

2022-05-21, 1401/02/31

Expected recruitment end date

2022-07-22, 1401/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of blended canola and Pistacia Atlantica seed oil compared with blended canola and corn oil with and without synthetic antioxidant TBHQ on serum oxidant and antioxidant status markers in patients with metabolic syndrome

Public title

The effect Pistacia Atlantica seed oil on serum antioxidant status in patients with metabolic syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Adults aged 20-50 years Diagnosed with metabolic syndrome (having at least three of these conditions): abdominal obesity (waist circumference >102 cm in men and >88 cm in women), high blood pressure (systolic blood pressure >130 mmHg or diastolic blood pressure >85 mmHg), low serum high-density lipoprotein cholesterol (serum HDL cholesterol <40 mg/dl in men and <50 mg/dl in women), high serum triglycerides (serum triglyceride > 150 mg/dl), high blood glucose (fasting blood glucose ≥ 100 mg/dl)

Exclusion criteria:

Diagnosis or reporting a history of cardiovascular disease Diagnosis or reporting a history of diabetes mellitus Diagnosis or reporting a history of cancer Diagnosis or reporting a history of pancreatitis Diagnosis or reporting a history of liver disease Diagnosis or reporting a history of kidney disease Changing the blood sugar and lipid-lowering medications over the past three months Taking systemic corticosteroids, androgen, phenytoin, erythromycin, Hemostatic regulators (other than aspirin), gastrointestinal medicine less than 30 days before enrollment History of gastrointestinal disorders Alcohol use Being pregnant Intention to become pregnant Giving birth in the last 12 months Having allergy or intolerance to the intervention oils Reluctance to follow the study protocol Having weight change over 3 kg two months prior to the study Taking Omega-3 supplements more than 1 g/day Smoking more than 20 cigarettes a day Taking drugs for COVID-19 including remdesivir, Interferon, actemra, favipiravir in the last 3 months

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

As a randomized and cross-sectional three-way clinical trial, stratified block randomization will be used to assign participants for receiving the intervention oils. The stratification will be done based on sex and the block size will be 6. The participants in each block will be randomly assigned to one of the 6 sequences of rolling method in order to consume the three intervention oils during the study period: 1) blended canola-Pistacia Atlantica seed oil in phase 1, blended Canola-corn oil (with TBHQ) in phase 2, blended Canola-corn oil (without TBHQ) in phase 3; 2) blended canola-Pistacia Atlantica seed oil in phase 1, blended Canola-corn oil (without TBHQ) in phase 2, blended Canola-corn oil (with TBHQ) in phase 3; 3) blended Canola-corn oil (with TBHQ) in phase 1, blended Canola-corn oil (without TBHQ) in phase 2, blended canola-Pistacia Atlantica seed oil in phase 3; 4) blended Canola-corn oil (with TBHQ) in phase 1, blended canola-Pistacia Atlantica seed oil in phase 2, blended Canola-corn oil (without TBHQ) in phase 3; 5) blended Canola-corn oil (without TBHQ) in phase 1, blended Canola-corn oil (with TBHQ) in phase 2, blended canola-Pistacia Atlantica seed oil in phase 3; 6) blended Canola-corn oil (without TBHQ) in phase 1, blended canola-Pistacia Atlantica seed oil in phase 2, blended Canola-corn oil (with TBHQ) in phase 3. The randomized allocation will be done by n independent statistician using the statistical package for social sciences (SPSS) software. The randomization will be concealed from researchers by using opaque sealed envelopes.

Blinding (investigator's opinion)

Triple blinded

Blinding description

In this study, blinding will be done for treatment oils for participants, researchers, and statisticians. The intervention oils will be given in the same bottles and will be coded for each oil (canola-Pistacia Atlantica seed oil, Canola-corn oil (with TBHQ), Canola-corn oil (without TBHQ)) by an independent person who is not familiar with the study protocol and objectives.

Placebo

Used

Assignment

Crossover

Other design features

The participants' spouses will attend all visits of the study and also will provide blood samples. The blood samples will be aliquoted and frozen in the form of serum, Buffy coat, and whole blood and stored for further research. No analysis will be done on their specimen and data in the current study.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of shahid sadoughi university of medical sciences
Street address
Central building of shahid sadoughi university of medical sciences, bahonar square, Yazd, Iran
City
Yazd
Province
Yazd
Postal code
8916978477
Approval date
2021-11-23, 1400/09/02
Ethics committee reference number
IR.SSU.SPH.REC.1400.167

Health conditions studied

1

Description of health condition studied
Metabolic Syndrome
ICD-10 code
E88.81
ICD-10 code description
Metabolic Syndrome

Primary outcomes

1

Description
Serum total antioxidant capacity (TAC)
Timepoint
Start and end of each intervention period
Method of measurement
IU/ml

2

Description
Serum myeloperoxidase (MPO)
Timepoint
Start and end of each intervention period
Method of measurement
ng/ml

3

Description
Serum malondialdehyde (MDA)
Timepoint
Start and end of each intervention period
Method of measurement
nmol to ml

4

Description
Serum total oxidant status (TOS)
Timepoint
Start and end of each intervention period
Method of measurement
IU/ml

5

Description
Serum superoxide Dismutase (SOD)
Timepoint
Start and end of each intervention period
Method of measurement
IU/ml

6

Description
Serum catalase (CAT)
Timepoint
Start and end of each intervention period
Method of measurement
IU/ml

7

Description
Serum glutathione peroxidase (GPX)
Timepoint
Start and end of each intervention period
Method of measurement
IU/ml

8

Description
Serum glutathione reductase (GR)
Timepoint
Start and end of each intervention period
Method of measurement
U/gr Hb

9

Description
Serum nitric oxide (NO)
Timepoint
Start and end of each intervention period
Method of measurement
Mm/ml

10

Description
Fasting serum glucose
Timepoint
Start and end of each intervention period

Method of measurement
using appropriate kits

11

Description
Serum triglycerides
Timepoint
Start and end of each intervention period
Method of measurement
mg/dL

12

Description
Serum high density lipoprotein cholesterol (HDL-C)
Timepoint
Start and end of each intervention period
Method of measurement
mg/dL

13

Description
Systolic blood pressure
Timepoint
Start and end of each intervention period
Method of measurement
Barometer

14

Description
Diastolic blood pressure
Timepoint
At the start and end of each intervention period
Method of measurement
Barometer

Secondary outcomes

1

Description
Body mass index (BMI)
Timepoint
Start and end of each intervention
Method of measurement
kg/m2

2

Description
Body fat percent
Timepoint
Start and end of each intervention
Method of measurement
Body composition analyzer

3

Description
Body muscle percent
Timepoint
Start and end of each intervention
Method of measurement
Body composition analyzer

4

Description
Body weight
Timepoint
Start and end of each intervention
Method of measurement
Body composition analyzer

Intervention groups

1

Description
Intervention phase: A blend of canola oil and Pistacia Atlantica seed oil (canola-Pistacia Atlantica seed oil)
Category
Lifestyle

2

Description
Intervention phase: canola–corn oil with TBHQ
Category
Lifestyle

3

Description
Intervention phase: canola–corn oil without TBHQ
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
School of Public Health, Shahid Sadoughi University of Medical Sciences
Full name of responsible person
Bahareh Sasanfar
Street address
School of Public Health, Shahid Sadoughi University of Medical Sciences, Alem Square, Yazd, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
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Chancellery for Research, Central Building of Shahid Sadoughi University of Medical Sciences, Bahonar square, Yazd, Iran
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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
Yazd University of Medical Sciences
Proportion provided by this source
33
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

2

Sponsor
Name of organization / entity
Neshatavar Food Industry (DATIS)
Full name of responsible person
Mrs Maryam Niktabe
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Ladan 5, ladan Blvd, Industrial zone,Yazd, Iran
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Phone
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Email
info@neshatavar.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Neshatavar Food Industry (DATIS)
Proportion provided by this source
67
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Industry

Person responsible for general inquiries

Contact
Name of organization / entity
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Full name of responsible person
Bahareh Sasanfar
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PhD student
Latest degree
Bachelor
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Person responsible for updating data

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Email
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is 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

Title and more details about the data/document
We plan to register and deposit data that relates to individual primary publications and not the whole study database. this enables other researchers to replicate published analyses and results as well as to re-use the data for additional analyses such as meta-analysis. general characteristics (without the identity of the participants) as well as baseline and after-treatment data value of primary and secondary outcome variables, will become available for researchers after a request from interested investigators.

When the data will become available and for how long
Data will be available after the individual related papers become published.

To whom data/document is available
Data will become available for all investigators interested in the subject.

Under which criteria data/document could be used
All efforts will be made to protect privacy and to de-identify the data. Therefore, data will be shared on request under the following conditions: -A meaningful study question by the requester; -Outline of the planned analyses; -Valid methodology; -signed data sharing agreement that contains a confidentiality agreement and approval of the study team members.

From where data/document is obtainable
The data can be obtained from the principal investigator: Dr.Amin Salehi Abargouei, MSc, PhD in nutrition. department of nutrition faculty of public health shahid sadoughi university of Medical sciences Yazd, PO code 8915173160 Iran, Tel:+98-35-31492229, Fax:+98-35-38209119, Email: abargouei@ssu.ac.ir Alternate email:abargouei@gmail.com

What processes are involved for a request to access data/document
The interested investigators should provide a brief description of the data needed and their reason for asking for the data by contacting the principal investigator. He will assess the possibility of sharing the data and if applicable will ask for a signed data sharing agreement that contains a confidentiality agreement and approval of the study team members.

Comments