

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of sesame-canola oil compared to sesame and canola oil on blood pressure, lipid profile and blood glucose control in patients with type 2 diabetes and their spouse: A three-way randomized cross-over clinical trial

Protocol summary

Study aim

To investigate the effect of replacing the regular oil consumption of participant (people with diabetes and their spouses) with sesame-canola (a blend of sesame and canola oil) in comparison with sesame oil and canola oil on blood pressure and cardiometabolic markers.

Design

Three-way randomized cross-over clinical trial

Settings and conduct

This study will be conducted at diabetes research center. All three types of oils will be provided for participants in the same packages labeled by a person who is not aware of the study objectives and protocol. Participants and personnel will be blinded to the intervention oil. Physical activity assessment, three-day weighted food record, anthropometric and blood pressure measurement will be conducted at the entrance, start, and the end of each intervention period and blood samples will also be taken from each participant (people with diabetes and their spouses) at the start and the end of each intervention period.

Participants/Inclusion and exclusion criteria

Patients with type 2 diabetes mellitus aged 18-60 years will be entered into the present study. Each participant will enter the study with his/her spouse. Participants on insulin therapy or a history of cardiovascular, kidney and liver diseases, and cancer will not be entered to the study.

Intervention groups

Each intervention period will last for nine weeks, four weeks apart as wash-out period (in which sunflower oil will be provided). The participants will be randomized using a software to receive sesame, canola and sesame-canola oils in each intervention period.

Main outcome variables

Serum total cholesterol, triglyceride, high density

lipoprotein cholesterol, low Density Lipoprotein cholesterol, and fasting blood sugar

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT2016091312571N6**

Registration date: **2016-11-14, 1395/08/24**

Registration timing: **registered_while_recruiting**

Last update: **2018-05-15, 1397/02/25**

Update count: **1**

Registration date

2016-11-14, 1395/08/24

Registrant information

Name

Amin Salehi-Abargouei

Name of organization / entity

Shahid Sadoughi University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 35 3820 9100

Email address

abargouei@hlth.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Sadoughi University of Medical Sciences, Yazd, Iran.

Expected recruitment start date

2016-05-07, 1395/02/18

Expected recruitment end date

2017-09-22, 1396/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of sesame-canola oil compared to sesame and canola oil on blood pressure, lipid profile and blood glucose control in patients with type 2 diabetes and their spouse: A three-way randomized cross-over clinical trial

Public title

The effect of sesame-canola oil compared to sesame and canola oil on patients with type 2 diabetes and their spouse

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Adults aged between 18-60 years old With clinically diagnosed type 2 diabetes for at least 6-month and maximum of 10 years With hemoglobin A1C lower than 8 percent Only take oral anti-hyperglycemic agents for the treatment have intention to enter the study and fill the informed consent

Exclusion criteria:

Being on insulin therapy History of known Cardiovascular Diseases (Coronary Artery Disease, Stroke, Congestive heart disease) Coronary artery bypass grafting (CABG) History of kidney or liver disease [alanine aminotransferase (ALT) and aspartate aminotransferase (AST) three times more than normal values] history of cancer Changing the dose of lipid lowering medications for at least 3 months prior starting the study being pregnant

Age

From **18 years** old to **60 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: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

As a three-way randomized controlled clinical trial the eligible participants will be randomly assigned to one of six following rolling methods using the statistical package for social sciences software (SPSS): 1) Sesame-

canola, sesame, canola; 2) Sesame-canola, canola, sesame; 3) Canola, sesame-canola, sesame; 4) Canola, sesame, sesame-canola; 5) Sesame, sesame-canola, canola and 6) Sesame, canola, sesame-canola.

Blinding (investigator's opinion)

Triple blinded

Blinding description

In this study, blinding will be done for treatment oils for both researchers and participants. The oils will be given in the same 2.5-liter bottles and will be coded for each oils (canola, sesame and sesame-canola) by someone who are not enroll in the study design .

Placebo

Not used

Assignment

Crossover

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committe 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

2016-05-29, 1395/03/09

Ethics committee reference number

IR.SSU.REC.1395.25

2**Ethics committee****Name of ethics committee**

Ethics committe of Shahid Sadoughi University of Medical Sciences

Street address

Central Building of Shahid Sadoughi University of Medical Sciences, Bahonar Square, Yazd, Iran

City

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Yazd

Postal code

8916978477

Approval date

2016-05-29, 1395/03/09

Ethics committee reference number

IR.SSU.REC.1395.26

Health conditions studied

1

Description of health condition studied

Non-insulin-dependent diabetes mellitus

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

2

Description of health condition studied

Spouses

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Serum high density lipoprotein cholesterol (HDL-C)

Timepoint

start and the end of each intervention period

Method of measurement

Using Appropriate kits, by Alpha-Classic autoanalyzer

2

Description

Serum fasting blood sugar(FBS)

Timepoint

start and the end of each intervention period

Method of measurement

using Appropriate kits, by Alpha-Classic autoanalyzer

3

Description

Serum low Density Lipoprotein cholesterol (LDL-C)

Timepoint

start and the end of each intervention period

Method of measurement

Using Appropriate kits, by Alpha-Classic autoanalyzer

4

Description

Serum Total cholesterol

Timepoint

start and the end of each intervention period

Method of measurement

using Appropriate kits, by Alpha-Classic autoanalyzer

5

Description

Serum triglyceride level (TG)

Timepoint

start and the end of each intervention period

Method of measurement

using Appropriate kits, by Alpha-Classic autoanalyzer

Secondary outcomes

1

Description

BMI(body mass index)

Timepoint

entrance and start and the end of each intervention period

Method of measurement

kg/m²

2

Description

Body Fat percent

Timepoint

entrance and start and the end of each intervention period

Method of measurement

by body composition analyzer

3

Description

Muscle mass percent

Timepoint

entrance and start and the end of each intervention period

Method of measurement

by body composition analyzer

4

Description

weight

Timepoint

entrance and start and the end of each intervention period

Method of measurement

by body Calibrated scale

5

Description

blood pressure

Timepoint

entrance and start and the end of each intervention period

Method of measurement

by Barometer

6

Description

Insulin

Timepoint

start and the end of each intervention period

Method of measurement

using Appropriate ELISA kit.

7

Description

Lipoprotein(a)

Timepoint

start and the end of each intervention period

Method of measurement

using Appropriate kits, by Alpha-Classic autoanalyzer

8

Description

Apo lipoprotein A (Apo A)

Timepoint

start and the end of each intervention period

Method of measurement

using Appropriate kits, by Alpha-Classic autoanalyzer

9

Description

Apo lipoprotein B(Apo B)

Timepoint

start and the end of each intervention period

Method of measurement

using Appropriate kits, by Alpha-Classic autoanalyzer

10

Description

Alkaline phosphatase (ALP)

Timepoint

start and the end of each intervention period

Method of measurement

using Appropriate kits, by Alpha-Classic autoanalyzer

11

Description

alanine aminotransferase (ALT)

Timepoint

start and the end of each intervention period

Method of measurement

using Appropriate kits, by Alpha-Classic autoanalyzer

12

Description

aspartate aminotransferase (AST)

Timepoint

start and the end of each intervention period

Method of measurement

using Appropriate kits, by Alpha-Classic autoanalyzer

13

Description

gama glutamil transferase (GGT)

Timepoint

start and the end of each intervention period

Method of measurement

using Appropriate kits, by Alpha-Classic autoanalyzer

14

Description

Urea

Timepoint

start and the end of each intervention period

Method of measurement

using Appropriate kits, by Alpha-Classic autoanalyzer

15

Description

creatinine

Timepoint

start and the end of each intervention period

Method of measurement

using Appropriate kits, by Alpha-Classic autoanalyzer

Intervention groups

1

Description

Intervention: Sesame-canola oli

Category

Lifestyle

2

Description

control: sesame oil

Category

Lifestyle

3

Description

Control: Canola oil

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Diabetes Research Center, Shahid Sadoughi
University of Medical Sciences

Full name of responsible person

Mojgan Amiri, Fatemeh Moghtaderi, Hamidreza Raeisi

Street address

diabetes Research Center, Bahonar Square, Yazd, Iran

City

Yazd

Province

Yazd

Postal code

8915173160

Phone

+98 35 3820 9100

Email

mojgan.amiri2015@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, shahid sadughi yazd
University of Medical Sciences

Full name of responsible person

Dr. Amirhushang Mehrparvar

Street address

Chancellery for research, Central Building of Shahid
Sadoughi University of Medical Sciences, Bahonar
Square, Yazd, Iran

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Phone

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Email

ah.mehrparvar@gmail.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice Chancellor for Research, shahid sadughi yazd
University of Medical Sciences

Proportion provided by this source

53

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

Street address

Ladan 5, Ladan Blvd, Industrial zone, Yazd, Iran

City

Yazd

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Yazd

Postal code

8915173160

Phone

+98 35 3727 5545

Email

info@neshatavar.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Neshatavar food industry (Datis)

Proportion provided by this source

47

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

Nutrition and Food security Research Center, Faculty
of Health, Shahid Sadoughi University of Medica

Full name of responsible person

Mojgan Amiri

Position

MSc student of Health Sciences in Nutrition

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

Street address

Department of Nutrition, Faculty of Public Health,
Shahid Sadoughi University of Medical Sciences, Alem
Square, Yazd, Iran.

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Phone

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Fax**Email**

mojgan.amiri2015@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Nutrition and Food security Research Center, Faculty
of Health, Shahid Sadoughi University of Medica

Full name of responsible person

Amin Salehi-Abargouei

Position

PhD in Nutrition Sciences

Latest degree

Ph.D.

Other areas of specialty/work**Street address**

Department of Nutrition, Faculty of Public Health,
Shahid Sadoughi University of Medical Sciences, Alem
Square, Yazd, Iran.

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Fax**Email**

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Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Nutrition and Food security Research Center, Faculty
of Health, Shahid Sadoughi University of Medical

Full name of responsible person

Mojgan Amiri

Position

MSc student of Health Sciences in Nutrition

Latest degree

Bachelor

Other areas of specialty/work

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Fax**Email**

mojgan.amiri2015@yahoo.com

Web page address**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

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

Title and more details about the data/document

baseline and after treatment data values of primary and
secondary outcome variables will be available for
researchers.

When the data will become available and for how long

Data will be available after the summary data become
published.

To whom data/document is available

The data will be available for all researchers interested in
the subject.

Under which criteria data/document could be used

Data will be available if the interested researcher(s) fills
the proposal for a joint project and the sponsor of the
study (Shahid Sadoughi University of Medical Sciences)
confirms the protocol of the project.

From where data/document is obtainable

The data can be obtained from Dr. Amin Salehi-
Abargouei, Ph.D. 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 the data by contacting the principal investigator.
The principal investigator will assess the possibility of
sharing the data and if applicable will ask for a joint
proposal. The joint proposal will be sent to the vice
chancellery for research, Shahid Sadoughi University of
Medical Sciences (the sponsor) and the data will be sent
by the principal investigator if the sponsor confirms the
cooperation.

Comments