

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of oral consumption of sesame oil on anthropometric, metabolic and oxidative stress markers of patients with type 2 diabetes

Protocol summary

Study aim

Determination of the effect of oral consumption of sesame oil on anthropometric, metabolic and oxidative stress markers of patients with type 2 diabetes

Design

A double-blind randomized clinical trial with 24 DM type 2 patients divide into intervention and control group

Settings and conduct

This randomized double-blind clinical trial will be performed in Kashan Shahid Beheshti hospital. Participants are DM type 2 patients divide into sesame oil (n=24) and control (n=24) group. The intervention period is 8 weeks.

Participants/Inclusion and exclusion criteria

Inclusion criteria: participants must be patients of type 2 diabetes and their diabetes have diagnosed at least 2 years ago the age range of 30 to 70 years; have no change in anti-diabetic medication since at least 4 weeks before the start of clinical trial; have HGA1C higher than 7% and lower than 9%; patients must be similar in anti-diabetic and statin drugs exclusion criteria: patients show the allergic reaction during intervention; medication changes; treatment shift to insulin; a significant change in physical activities; hyperthyroidism or hyperthyroidism; pregnancy or lactation.

Intervention groups

DM type 2 patients divide into sesame oil and control group (15 gram oil per day in both groups). The lab tests in each participant will be done before and after 8 weeks of intervention. Sunflower oil will be used for placebo group, to be the closest type of oil to sesame oil.

Main outcome variables

Blood pressure, blood sugar, LDL, HDL, Triglyceride, Cholesterol, Malondialdehyde, Total Antioxidant Capacity, Glutathione, C-reactive protein

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150920024103N2**
Registration date: **2020-07-04, 1399/04/14**
Registration timing: **prospective**

Last update: **2020-07-04, 1399/04/14**

Update count: **0**

Registration date

2020-07-04, 1399/04/14

Registrant information

Name

Sadegh Jafarnejad

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 5554 0021

Email address

sjafarnejad@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-25, 1399/05/04

Expected recruitment end date

2020-08-25, 1399/06/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of oral consumption of sesame oil on anthropometric, metabolic and oxidative stress markers

of patients with type 2 diabetes

Public title

The effect of oral consumption of sesame oil on patients with type 2 diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Participants must be patients of type 2 diabetes and their diabetes have diagnosed at least 2 years ago (FBG ≥ 125 mg/dl, (OGTT) ≥ 200 mg/dl, HbA1C ≥ 7 and blood sugar ≥ 200 mg/dl) Have nearly similar economic and social situation Have no change in anti-diabetic medication since at least 4 weeks before the start of clinical trial Have HGA1C higher than 7% and lower than 9% Patients must be similar in anti-diabetic and statin drugs Patients should not be smoking and alcohol consumer

Exclusion criteria:

Patients show the allergic reaction during the intervention Medication changes or treatment shift to insulin Significant change in physical activities Hyperthyroidism or hyperthyroidism Pregnancy or lactation Omega 3 Supplement consumption Patients suffer from any type of inflammation, organs failure, Corticosteroids consumption and GFR rate under 30

Age

From **30 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization. For simple randomization, we are going to use "random digits table" in "Stat Trek" application.

Blinding (investigator's opinion)

Double blinded

Blinding description

This is a double-blind study. Participants who participated in the study consciously, and the researchers in this study are blind and unaware that each of either participants is in one of the placebo or intervention groups.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kashan University of Medical Sciences

Street address

Ghotbravandi Blvd, Kashan

City

Kashan

Province

Isfahan

Postal code

8115187159

Approval date

2019-07-30, 1398/05/08

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1398.055

Health conditions studied

1

Description of health condition studied

Diabetes type 2

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

Primary outcomes

1

Description

Anthropometric measurements

Timepoint

Before and after intervention

Method of measurement

Height meters and weighing Scale

2

Description

Fasting blood sugar

Timepoint

Before and after intervention

Method of measurement

Laboratory kit

3

Description

Triglycerides

Timepoint

Before and after intervention

Method of measurement

Enzymatic kit

4

Description

High density lipoprotein

Timepoint

Before and after intervention

Method of measurement

Enzymatic kit

5

Description

Low density lipoprotein

Timepoint

Before and after intervention

Method of measurement

Enzymatic kit

6

Description

Cholesterol

Timepoint

Before and after intervention

Method of measurement

Enzymatic kit

7

Description

C-reactive protein

Timepoint

Before and after intervention

Method of measurement

ELISA kit

8

Description

Total antioxidant capacity

Timepoint

Before and after intervention

Method of measurement

Spectrophotometry

9

Description

GSH

Timepoint

Before and after intervention

Method of measurement

Spectrophotometry

10

Description

MDA

Timepoint

Before and after intervention

Method of measurement

Spectrophotometry

Secondary outcomes

1

Description

Insulin resistance

Timepoint

before and after intervention

Method of measurement

Elisa Kit

2

Description

Insulin sensitivity

Timepoint

Before and after intervention

Method of measurement

Elisa Kit

Intervention groups

1

Description

Intervention group: oral consumption of sesame oil, 15 gram/day during 8 weeks

Category

Treatment - Other

2

Description

Control group: oral consumption of sunflower oil , 15 gram/day during 8 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital

Full name of responsible person

Dr. Mashallah Tabatabaei Zadeh

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beheshtihospital@kaums.ac.ir

2

Recruitment center

Name of recruitment center

Akhavan hospital

Full name of responsible person

Mohammad Tobeiha

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15 Khordad square. , Kashan, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Hamid Reza Banafshe

Street address

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banafshe57@hotmail.com

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

Yes

Title of funding source

Kashan 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

Kashan University of Medical Sciences

Full name of responsible person

Sadegh Jafarnejad

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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assistant professor

Latest degree

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Person responsible for updating data

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Negin Amin

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master of science student in nutrition science

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

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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

Undecided - It is not yet known if there will be 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