Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Investigation of the effect of pistachio plant fixed oil (Pistacia atlantica subsp. Kurdica) (as softgel) on control of blood sugar, lipid profile, inflammatory factors and oxidative stress in people with type 2 diabetes: Double-blind randomized clinical trial

Protocol summary

Study aim

Determining the effect of essential oil of pistachio (Pistacia atlantica subsp. Kurdica) on the control of blood sugar, lipid profile, inflammatory factors, and oxidative stress in patients with type 2 diabetes and its comparison with the control group

Design

Two arms parallel-group randomized trial with control group, double-blind, phase 2 on 70 patients, randomization software (RAS) was used for randomization.

Settings and conduct

70 people with type 2 diabetes referred to the Diabetes Clinic of Taleghani Hospital are selected by physicians according to the criteria of the American Diabetes Association. Individuals will be randomly divided into two groups: placebo and intervention. Researchers and participants were blinded by the study group. The codes assigned to each participant are grouped by an unaware person to the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Being over 18 years old, Having 2 years of history of type 2 diabetes according to the American Diabetes Association criteria, Body mass index (BMI) greater than or equal to 25 kg/m2; Exclusion criteria: Pregnancy, Lactation, Insulin injection, People with autoimmune diseases, People with gastrointestinal diseases, People with liver disease, People with kidney disease, People with cardiovascular disease, People with a severe respiratory illness, Consumption of any vitamins, minerals, and dietary supplements, Alcohol consumption, Consumption of plant sterols, Consumption of psyllium, Consumption of fish oil, Existence of allergies to pistachio plant species

Intervention groups

Intervention group: 1500 mg of pistachio oil three times per day with each meal. Placebo group: 1500 mg of soft gel placebo daily with the same shape, color, and size. The duration of the intervention will be 12 weeks.

Main outcome variables

Fasting blood sugar, LDL cholesterol, High-sensitivity C-reactive Protein

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200912048693N2**
Registration date: **2021-02-25, 1399/12/07**
Registration timing: **prospective**

Last update: **2021-02-25, 1399/12/07**
Update count: **0**

Registration date

2021-02-25, 1399/12/07

Registrant information

Name
Amir Saber

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 83 3710 2009

Email address
amir.saber@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-20, 1400/02/30

Expected recruitment end date

2021-09-21, 1400/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of the effect of pistachio plant fixed oil (Pistacia atlantica subsp. Kurdica) (as softgel) on control of blood sugar, lipid profile, inflammatory factors and oxidative stress in people with type 2 diabetes: Double-blind randomized clinical trial

Public title

Evaluation of the effect of pistachio oil on people with type 2 diabetes

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Having a 2-year history of type 2 diabetes according to the American Diabetes Association criteria Body mass index (BMI) greater than or equal to 25 kg/m2

Exclusion criteria:

Pregnancy Lactation Insulin injection People with autoimmune diseases People with gastrointestinal diseases People with liver disease People with kidney disease People with thyroid disease People with cardiovascular disease People with severe respiratory illness such as asthma and chronic bronchitis Consumption of any vitamins, minerals and dietary supplements Alcohol consumption Consumption of plant sterols Consumption of psyllium Consumption of fish oil Existence of allergies to pistachio plant species

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, the randomization method is simplified and it is individual randomization so that, after meeting the inclusion criteria, each person is assigned a random code created by random allocation software (RAS). After that, these codes are randomly divided into two groups as intervention and control groups by a third person who is unaware of the study and its conditions.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants in this study do not know whether they are in the intervention or control group, Researchers do not know which participant is in the intervention or control group. In order to blindness, each participant in the study is assigned a random code created by random allocation software (RAS), and these codes are divided into two groups by a third person who is unaware of the study and its conditions.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kermanshah University of Medical Sciences

Street address

Faculty of Nutritional Sciences and Food Industry, next to Farabi hospital, Esar square, Kermanshah

City

Kermanshah

Province

Kermanshah

Postal code

6719851552

Approval date

2021-02-16, 1399/11/28

Ethics committee reference number

IR.KUMS.REC.1399.1110

Health conditions studied

1

Description of health condition studied

Type 2 diabetes mellitus

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

Primary outcomes

1

Description

Fasting blood sugar

Timepoint

At the beginning of the study (before the intervention) and at the end of the study

Method of measurement
Glucose oxidase assay

2

Description
LDL cholesterol
Timepoint
At the beginning of the study (before the intervention) and at the end of the study
Method of measurement
Direct enzymatic method

3

Description
High-sensitivity C-reactive Protein
Timepoint
At the beginning of the study (before the intervention) and at the end of the study
Method of measurement
Enzyme-Linked Immunosorbent Assay

Secondary outcomes

1

Description
Hemoglobin A1C
Timepoint
At the beginning of the study (before the intervention) and at the end of the study
Method of measurement
Enzymatic assay

2

Description
Total cholesterol
Timepoint
At the beginning of the study (before the intervention) and at the end of the study
Method of measurement
Enzymatic assay

3

Description
Tumor necrosis factor-alpha
Timepoint
At the beginning of the study (before the intervention) and at the end of the study
Method of measurement
Enzyme-Linked Immunosorbent Assay

4

Description
Interleukin-6
Timepoint
At the beginning of the study (before the intervention) and at the end of the study
Method of measurement
Enzyme-Linked Immunosorbent Assay

5

Description
Interleukin-10
Timepoint
At the beginning of the study (before the intervention) and at the end of the study
Method of measurement
Enzyme-Linked Immunosorbent Assay

6

Description
Malondialdehyde
Timepoint
At the beginning of the study (before the intervention) and at the end of the study
Method of measurement
Reactivity with thiobarbituric acid

7

Description
Total antioxidant capacity
Timepoint
At the beginning of the study (before the intervention) and at the end of the study
Method of measurement
Colorimetric method

Intervention groups

1

Description
Intervention group: Consumption material: Ripe pistachio fruit oil; Chemical composition and concentration: α-Pinene (30.1%), Oxygenated monoterpenes (21.2 %), Sesquiterpene hydrocarbons (9.6 %), Bornyl acetate (8.5 %), Camphene (5.7 %), Myrcene (5.4 %), Spathulenol (5.3 %), α-Terpineol (4.1 %), Limonene (3.8 %), Germacrene D (2.7 %), α-Terpinolene (2.1 %) and other constituents (1.5 %); Dosage: 1500 mg per day; Daily usage: 3 times a day; Duration of use: 12 weeks; How to use: orally 500 mg soft gel; 500 mg soft gels are produced by Zahravi Pharmaceutical Company after oil extraction from ripe pistachio fruit by cold press method.
Category
Rehabilitation

2

Description
Control group: Consumption material: soybean oil; Chemical composition and concentration: palmitic acid (10%), stearic acid (4%), oleic acid (18%), linoleic acid (55%), and linolenic acid (13%); Dosage: 1500 mg per day; Daily usage: 3 times a day; Duration of use: 12 weeks; How to use: orally 500 mg soft gel; After purchasing soybean oil, 500 mg soft gels are produced by Zahravi Pharmaceutical Company.

Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Diabetes Clinic of Taleghani Hospital, Kermanshah University of Medical Sciences
Full name of responsible person
Amir Saber
Street address
Diabetes Clinic, Taleghani Hospital, Kermanshah
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Deputy of Research and Technology, Building No. 2, Shahid Beheshti Blvd.
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rkhodarahmi@kums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Vice Chancellor for Research, Kermanshah 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
Kermanshah University of Medical Sciences
Full name of responsible person
Amir Saber
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
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Person responsible for scientific inquiries

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Person responsible for updating data

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Position
Assistant Professor

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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
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All data related to the primary and secondary outcome will be shared

When the data will become available and for how long
Access starts 6 months after the results are published

To whom data/document is available
Researchers in academic and scientific institutions, as well as people in the industry, are allowed to access the data

Under which criteria data/document could be used
Anyone who request our data should provide a brief explanation of the purpose and method of their meta-analysis study. The applicant's request will be reviewed by the researchers and if all agree, the requested data will be sent to the applicant via email in the form of an Excel file. All of these steps will not take more than 10 days.

From where data/document is obtainable
Amir Saber, Assistant Professor, Kermanshah University of Medical Sciences, Faculty of Nutrition Sciences and Food Industry, Address: Faculty of Nutrition Sciences and Food Industry, Next to Farabi hospital, Esar Square, Kermanshah Postal code: 6719851552 Phone: 0098 83 37102009 Email: amir.saber@kums.ac.ir

What processes are involved for a request to access data/document
After sending the request by the applicant and confirming the goals and method of the study by all project researchers, the data will be provided by email in less than 10 days.

Comments