Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 Jul 2026

The effects of flaxseed oil supplementation in Glycemic control and body composition on overweight pre-diabetes patients

Protocol summary

Study aim

Determination of the Effect of Supplementation of flaxseedOil on Glycemic Control in Pre-Diabetes Patients with Overweight

Design

In this study, 40 individuals with pre-diabetes who are referred to the Isfahan Cardiovascular Center are eligible to enter the study. Participants are randomly divided into intervention and control groups and assigned to each participant a code.

Settings and conduct

This is a double-blind controlled clinical trial of overweight pre-diabetic individuals. At the beginning of the study, general information questionnaire including age, height, weight, occupation, history of disease, type and dosage of consumable drugs will be completed. Then, the subjects will be randomly divided into two groups and consumed flaxseed oil (1 g, 2 times a day) and placebo (1 g, 2 times a day) for 14 weeks. The participants in the study, a researcher and a clinical expert will be not aware on the type of supplementation used in each group. Serum samples from the participants at the beginning and end of the study will be collected by blood sampling and centrifugation. At the end of the study, Fasting Insulin, FBS and HOMA-IR, QUIKI-IR will be used. The completion of the three-day registration of the food intake and the physical activity registration questionnaire will be carried out at the beginning of the study and the end of the seventh and fourteenth weeks.

Participants/Inclusion and exclusion criteria

Inclusion criteria include those with fasting blood glucose levels between 100 and 125 mg / dL, with a body mass index of 25 to 29.9. Exclusion criteria: Getting oral hypoglycemic drugs and insulin injections, getting any acute and chronic disease, any kind of allergy or intolerance to your seed oil, smoking, having severe activity and unusual diet, women having a monthly cycle of at least 6 Last month, use of anti-inflammatory drugs as a base, having regular intake of thy juice, flaxseed oil or fish oil supplements, fish consumption of more than 340 g per week, and soy consumption, once or more than once a week, fixed

Intervention groups

The intervention group that receive flaxseed oil for 14 weeks daily(2 capsules of 1000 mg of oil per day), and the control group that received the same oral administration as the intervention group containing paraffin oil for (2 capsules of 1000 mg per day).

Main outcome variables

Fbs ؛ insulin

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120913010826N27**
Registration date: **2018-02-07, 1396/11/18**
Registration timing: **registered_while_recruiting**

Last update: **2018-03-13, 1396/12/22**
Update count: **1**

Registration date

2018-02-07, 1396/11/18

Registrant information

Name

Azadeh Nadjarzadeh

Name of organization / entity

Shahid Sadoughi University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2017-11-06, 1396/08/15
Expected recruitment end date
2017-12-06, 1396/09/15
Actual recruitment start date
2017-12-07, 1396/09/16
Actual recruitment end date
2018-03-06, 1396/12/15
Trial completion date
empty

Scientific title
The effects of flaxseed oil supplementation in Glycemic control and body composition on overweight pre-diabetes patients

Public title
Effect of flaxseed oil on pre-diabetes control
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Fasting blood glucose should be between 100 and 125 mg / dL The body mass index is between 25 and 29.9.
Exclusion criteria:
Receive oral hypoglycemic drugs and insulin injections Cure for any type of acute and chronic disease Any kind of allergy or intolerance to your seed oil smoking Having severe activity and unusual diet Women having a monthly cycle for at least 6 months Use of anti-inflammatory drugs Having regular consumption of your seed, flaxseed oil, fish oil, fish and soy supplement
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **40**
Actual sample size reached: **36**
Randomization (investigator's opinion)
Randomized
Randomization description
Individuals are randomly assigned to one of two study groups with the help of a random number table and received the intervention of the same group.
Blinding (investigator's opinion)
Double blinded
Blinding description
Participants, clinical caregivers and investigators will not be aware of the type of intervention. And the intervention in each group will be marked with codes A and B.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
کمیته اخلاق دانشگاه علوم پزشکی شهید صدوقی
Street address
Campus of Sadoughi University of Medical Sciences, Shohadaye Gomnam Blv,Yazd
City
Yazd
Province
Yazd
Postal code
8915173160
Approval date
2016-11-30, 1395/09/10
Ethics committee reference number
IR.SSU.SPH.REC.1396.20

Health conditions studied

1

Description of health condition studied
Prediabet
ICD-10 code
R73.02
ICD-10 code description
Impaired glucose tolerance (oral)

Primary outcomes

1

Description
Fasting insulin
Timepoint
Before the intervention and 14 weeks after the intervention
Method of measurement
Blood test, µU/ml

Secondary outcomes

1

Description
Weight
Timepoint
Before the intervention and 14 weeks after the intervention

Method of measurement
With scale

2

Description
Fbs
Timepoint
Before the intervention and the end of the week 14
Method of measurement
Blood test، mg/dl

Intervention groups

1

Description
Intervention group: To the intervention group, for 2 weeks, 2 capsules of 1000 mg of linseed oil will be given to the Barij Essen Pharmaceutical Company in Kashan. Given the length of the study, 196 capsules are for each person
Category
Prevention

2

Description
Intervention group: To placebo recipients, during the same periodic study, a placebo will be given to the recipient of the supplementation of flaxseed oil containing oral paraffin from the pharmaceutical company Barij Essen in Kashan. Given the length of the study, 196 capsul.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Jinan Diabetes Charity Association
Full name of responsible person
Aghaie
Street address
Danesh Ave, Shariati St., Najaf Abad, Isfahan
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Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Dr. Azadeh Najarzadeh
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Sadoughi University of Medical Sciences, shahid bahonar sq,Yazd
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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
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
Yazd University of Medical Sciences
Full name of responsible person
Dr.Azadeh Nadjarzadeh
Position
Associate Professor, nutrition specialist
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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Position
Associate Professor, nutrition specialist

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Nutrition

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Person responsible for updating data

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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
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not 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
Not applicable

Title and more details about the data/document
Data report will be shared after publishing the paper.

When the data will become available and for how long
Six months after publish

To whom data/document is available
Academic researchers

Under which criteria data/document could be used
Using for Meta-analysis

From where data/document is obtainable
Center nutrition, public health, univercity of medical sciencies yazd Tel: 009835 31492239 Email: azadehnajarzadeh@gmail.com Azadenadjarzadeh

What processes are involved for a request to access data/document
It will be sent two weeks after the receipt of the email with the consent of the co-workers

Comments