

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 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)

Phone

+98 912 202 2817

Email address

azadnadjarzadeh@ssu.ac.ir

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 Gornam 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

City

Najaf Abad

Province

Isfahan

Postal code

85137-94791

Phone

Email

janan.ansar@gmail.com

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

Street address

Sadoughi University of Medical Sciences, shahid bahonar sq,Yazd

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Postal code

8915173160

Email

azadehnajarzadeh@gmail.com

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

Street address

Department of nutrition, school of public health,shahid sadoughi university of medical sciences, Yazd, Iran

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Email

Person responsible for scientific inquiries

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

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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, university of medical sciences 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