

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jun 2026

### The effects of Flaxseed oil supplementation on inflammatory markers in overweight pre-diabetes patients

#### Protocol summary

##### Study aim

Determine the effect of flax seed oil supplement on inflammatory indexes in overweight pre-diabetes patients

##### Design

In this study, 80 pre-diabetic and eligible patients who are referred to the Isfahan Cardiovascular Center are selected. Participants are randomly divided into two intervention and control groups and each participant is given an assigned code.

##### Settings and conduct

This is a double-blind, randomized controlled clinical trial of overweight pre-diabetic individuals referred to the Isfahan Cardiovascular Center. At the beginning of the study, general information questionnaire including age, height, weight, occupation, history of disease, type and dosage of consumable drugs are completed. Then, the subjects were 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. Serum samples of the participants in the study were collected at the beginning and the end of the study by blood sampling and centrifugation. At the end of the study, was used to measure hs-CRP and TNF $\alpha$ . Participants will receive special codes for the control and intervention group that the investigator and the participants do not know about the type of intervention of each individual.

##### Participants/Inclusion and exclusion criteria

The inclusion criteria included people with impaired fasting glucose, fasting blood sugar of between 100 and 125 mg / dl, and body mass index of between 25 and 29/9. Exit criteria From the study included Receiving oral hypoglycaemic drugs (sulfonylurea, magnetlonid, bialuanides, thiazolidinedione, alpha-glucosidase inhibitors, DPP-4 inhibitors, SGLT2 inhibitors and insulin injections, any type of acute and chronic disease other than impaired glucose tolerance which affect on The metabolism of glucose or uncontrolled, any kind of susceptibility or intolerance to flaxseed oil, smoking,

having severe activity, and an unusual diet (more than 150 minutes of moderate aerobic activity per week or 75 minutes of aerobic activity with intensity Highly in the week, removing one or more food groups from the daily diet), women with Having a monthly cycle for at least the past 6 months, using basic anti-inflammatory drugs (steroidal and non-steroidal anti-inflammatory drugs), consuming regularly, flaxseed or fish oil supplements (one-time use or more per week for a fixed dose), and The consumption of fish is more than 340 grams per week and soy consumption is fixed at once or more than once a week

##### Intervention groups

The subjects in the intervention group will receive flaxseed oil supplement (two 1000-mg capsules per day, Barij Essence Co., Kashan) for 14 weeks. On the other hand, the subjects in the control group will take a placebo similar to the compound of the other group, which contained oral paraffin (two 1000-mg capsules per day).

##### Main outcome variables

TNF $\alpha$ ; hs-CRP

#### General information

##### Reason for update

##### Acronym

YDS

##### IRCT registration information

IRCT registration number: **IRCT20120913010826N26**

Registration date: **2018-02-05, 1396/11/16**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-02-05, 1396/11/16**

Update count: **0**

##### Registration date

2018-02-05, 1396/11/16

##### 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**

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**Recruitment status**

**Recruitment complete**

**Funding source**

Yazd University of Medical Sciences

**Expected recruitment start date**

2018-02-04, 1396/11/15

**Expected recruitment end date**

2018-03-20, 1396/12/29

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effects of Flaxseed oil supplementation on inflammatory markers in overweight pre-diabetes patients

**Public title**

The effect of Flaxseed oil on pre-diabetes

**Purpose**

Prevention

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

The body mass index is between 25 and 29.9. Fasting blood sugar is greater than or equal to 100 and less than 126 mg / dL.

**Exclusion criteria:**

Receive oral hypoglycemic drugs and insulin injections. Cure for any type of acute and chronic disease other than impaired glucose tolerance. Any kind of allergy or intolerance to Linseed 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 or Fish oil supplements Pregnancy and lactation

**Age**

No age limit

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Care provider
- Investigator

**Sample size**

Target sample size: **80**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Using the randomized code obtained from the computer

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

No external person was involved in the preparation of a randomized list, nor in the counting and packaging of capsules. All participants in this study (patients, health care provider) were unaware of the outcome of the treatment.

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

Yazd Shahid Sadoughi University of Medical Sciences

**Street address**

Campus of Sadoughi University of Medical Sciences, Shohadaye Gomnam Blv, Yazd

**City**

Yazd

**Province**

Yazd

**Postal code**

8915173160

**Approval date**

2016-10-22, 1395/08/01

**Ethics committee reference number**

ir.ccu.sph.rec.1395.118

**Health conditions studied**

**1**

**Description of health condition studied**

Pre-diabetes

**ICD-10 code**

R73.02

**ICD-10 code description**

Impaired glucose tolerance (oral)

**Primary outcomes**

**1**

**Description**

Crp

**Timepoint**

Before the intervention and 14 weeks after the

intervention  
**Method of measurement**  
Blood test.mg/l

2

**Description**  
TNF $\alpha$   
**Timepoint**  
Before the intervention and the end of the week 14  
**Method of measurement**  
Blood test.Pgr/ml

## Secondary outcomes

1

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

2

**Description**  
Weight  
**Timepoint**  
Before the intervention and the end of the week 14  
**Method of measurement**  
Balance, kg

## Intervention groups

1

**Description**  
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**  
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 capsu  
**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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Isfahan  
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janan.ansar@gmail.com  
**Web page address**

## Sponsors / Funding sources

1

**Sponsor**  
**Name of organization / entity**  
Shahid Sadoughi University of Medical Sciences Yazd  
**Full name of responsible person**  
Dr. Azadeh Najarzadeh  
**Street address**  
Sadoughi University of Medical Sciences, shahid bahonar sq,Yazd  
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**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**  
Shahid Sadoughi University of Medical Sciences Yazd  
**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**

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Department of nutrition, school of public health,  
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**Full name of responsible person**

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**Person responsible for updating data**

**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  
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**Email**

azadnajarzadeh@ssu.ac.ir

**Web page address**

**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  
scienicies 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**