

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Effect of flaxseed on insulin resistance and oxidative stress in prediabetic patients

Protocol summary

Summary

This study is designed to assess the effect of flaxseed on insulin resistance and oxidative stress in prediabetic patients. In this randomized controlled clinical trial, prediabetic patients ($n=90$), recruited from Shiraz University of Medical Science clinics, enter the study by inclusion criteria: prediabetic men or women aged 30 to 65 years, a fasting blood sugar of 100 -125mg/ dL or a two-hour blood sugar between 140 to 199 mg/ dL, body mass index of 25 - 34.9. Patients who are diagnosed with diabetes or receiving flaxseed or omega-3 supplements within the last three months will be excluded. They are assigned randomly to three groups: flaxseed (40 gr) and flaxseed (20 gr) as intervention groups and third group as control group. Participants on intervention groups are instructed to consume 20 and 40 gr flaxseed for 3 months, in exchange of same amount of carbohydrate and fat in daily diet and control group receive no intervention. Anthropometric, dietary evaluation, laboratory tests including, glycemic profile and insulin resistance, serum malondialdehyde and serum total antioxidant capacity tests are performed both before and after intervention in three groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013051313308N1**

Registration date: **2013-06-17, 1392/03/27**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-06-17, 1392/03/27

Registrant information

Name

Afrooz Javidi

Name of organization / entity

Shahid Sadoughi University of Medical
Science, International branch

Country

Iran (Islamic Republic of)

Phone

+98 35 1836 7668

Email address

afrooz.javidi@gmail.com

Recruitment status

Recruitment complete

Funding source

a budget that related to the thesis of masters degree and Vice chancellor for research, Shahid Sadoughi University of Medical Sciences

Expected recruitment start date

2013-05-22, 1392/03/01

Expected recruitment end date

2013-07-22, 1392/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of flaxseed on insulin resistance and oxidative stress in prediabetic patients

Public title

Flaxseed and prediabetes

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: willing to follow study protocol, scheduling, and testing location; men and women 30 to 65 years; Body mass index (BMI) of 25 - 34.9 Kg / m²

;prediabetic patients with fasting blood sugar of 100-125mg/ dl or a two-hour blood sugar between 140 to 199 mg/ dl;not using Insulin ang other glucose lowering medicatins;non smoking status; not using herbal , antioxidant supplementation and omega-3 until 3 months before intervention;without any history of gastrointestinal and kindney disorder;without any acute thyroid, kidney, liver, CVD diseases Exclusion criteria:unwillingness to follow study protocol, scheduling, and testing location;diagnosis of type 2 diabetes;smoking at least 2 tmes a week;regular history of flaxseed or flaxseed oil supplement or any omega-3 supplement intake ;taking glucose lowering drugs or insulin or estrogen or progesterone drugs ;pregnancy and lactation

Age

From **30 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Shahid Sadoughi University of Medical Science

Street address

International campus of Shahid Sadoughi University of Medical Science, 5th kilometer of Fahraj-Khavidak road, Yazd

City

Yazd

Postal code

8944157963

Approval date

2013-05-19, 1392/02/29

Ethics committee reference number

34132

Health conditions studied**1****Description of health condition studied**

prediabetes

ICD-10 code

R73.0

ICD-10 code description

Impaired glucose tolerance prediabetes

Primary outcomes**1****Description**

serum concentration of MDA

Timepoint

before and 3 months after intervention

Method of measurement

with spectrophotometer

2**Description**

serum total antioxidant capacity

Timepoint

before and 3 months after intervention

Method of measurement

cation decolorization assey ABTS

3**Description**

Insulin resistance

Timepoint

before and 3 months after intervention

Method of measurement

HOMA-IR index

4**Description**

beta-cell function

Timepoint

before and 3 months after intervention

Method of measurement

ELISA kit

5**Description**

Insulin sensitivity

Timepoint

before and 3 months after intervention

Method of measurement

QUICKI index

Secondary outcomes

1

Description

weight

Timepoint

before and after intervention

Method of measurement

scale with accuracy 100 gr

2

Description

Height

Timepoint

before and after intervention

Method of measurement

tape meter installed on the wall

3

Description

BMI(Body Mass Index)

Timepoint

before and after intervention

Method of measurement

Calculation:Weight (kg) / squared height (m)

4

Description

Total energy intake

Timepoint

before and after intervention

Method of measurement

24 hour recall

5

Description

carbohydrate intake

Timepoint

before and after intervention

Method of measurement

24 hour recall

6

Description

protein intake

Timepoint

before and after intervention

Method of measurement

24 hour recall

7

Description

fat intake

Timepoint

before and after intervention

Method of measurement

24 hour recall

8

Description

fiber intake

Timepoint

before and after intervention

Method of measurement

24 hour recall

9

Description

saturated fatty acid intake

Timepoint

before and after intervention

Method of measurement

24 hour recall

10

Description

mono unsaturated fatty acid intake(MUFA)

Timepoint

before and after intervention

Method of measurement

24 hour recall

11

Description

poly unsaturated fatty acid intake(PUFA)

Timepoint

before and after intervention

Method of measurement

24 hour recall

Intervention groups

1

Description

In first intervention group, prediabetic individuals, aged 30-65 years, will receive a daily allotment of 20 gr ground flaxseed for 12 weeks. They will be instructed to incorporate the supplement in their daily meals using the method described in the instruction pamphlet. They are instructed to substitute flaxseed for some of their usual carbohydrate and fat consumed at the meal. The subjects are told not to change diet and activity level.

Category

Treatment - Other

2

Description

In second intervention group, prediabetic individuals, aged 30-65 years, will receive a daily allotment of 40 gr ground flaxseed for 12 weeks. They will be instructed to incorporate the supplement in their daily meals using the method described in the instruction pamphlet. They are instructed to substitute flaxseed for some of their usual carbohydrate and fat consumed at the meal. The subjects are told not to change diet and activity level.

Category

Treatment - Other

3**Description**

In control group, prediabetic individuals, aged 30-65 years, will receive no intervention. The subjects are told not to change diet and activity level.

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shiraz University of Medical Science

Full name of responsible person

Dr. Mohammad Hasan Eftekhari

Street address

School of Health and Nutrition, Fatholmobin alley,
Kooye Zahra street, Shiraz, Iran

City

Shiraz

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shahid Sadoughi University of Medical
Science, International branch

Full name of responsible person

Dr. Mohammad Hasan Sheikha

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International campus of Shahid Sadoughi University
of Medical Science, 5th kilometer of Fahraj-Khavidak
road, Yazd

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Yazd

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
Science, International branch

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

Shahid Sadoughi University of Medical Science-
International branch

Full name of responsible person

Afrooz Javidi

Position

MSc student of health science in nutrition

Other areas of specialty/work**Street address**

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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PhD of Nutrition, professor

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Shahid Sadoughi University of Medical
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Afrooz Javidi

Position

MSc student

Other areas of specialty/work**Street address**

International campus of Shahid Sadoughi University
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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty