

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

The effect of flaxseed powder consumption on lipid profile, hypertention and C-Reactive Protein in dyslipidemic and hypertensive patients

Protocol summary

Summary

This study is a double blind clinical trial on 80 patients with hypertension and dyslipidemia. The study process can be summarized in three steps: 1) the preparation of flaxseed powder and placebo in sachet form by Kamvar company, Isfahan, Iran. Participants will consume either 36 gram flaxseed sachet or 12 gram placebo sachet per day during study. 2) At first, form referring patients to affiliated clinics with Isfahan university of medical sciences, 80 patients with dyslipidemia and high blood pressure will be selected based on inclusion criteria by a cardiologist and after that will be recruited to this study. After taking informed written consent, patients will randomly be assigned to either intervention group (36 gram flaxseed sachet per day) or placebo group (12 gram sachet placebo per day) for 8 week. Biochemical assessment including lipid profiles (TG, LDL-C, HDL-C, Total-C), C-reactive protein, fasting blood sugar, anthropometric indices (weight, height, waist circumference, hip circumference, waist to hip ratio), systolic and diastolic blood pressure and physical activity will be measured at the beginning and end of study. 3-day dietary record will be obtained from all participants at week 0, 4 and 8. 3) Data will be analyzed by using SPSS software.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016081611763N28**

Registration date: **2017-06-30, 1396/04/09**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-06-30, 1396/04/09

Registrant information

Name

Gholamreza Askari

Name of organization / entity

Isfahan University of Medical Sciences

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Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2016-12-21, 1395/10/01

Expected recruitment end date

2017-04-04, 1396/01/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of flaxseed powder consumption on lipid profile, hypertention and C-Reactive Protein in dyslipidemic and hypertensive patients

Public title

Flaxseed powder and cardiovascular risk factor

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Triglyceride concentrations more than 150; Total cholesterol levels more than 200; LDL-C levels more than 130; HDL-C levels less than 40 mg per dl; blood pressure equal to or more than 140/90 mmHg.

Exclusion criteria: Pregnancy ; Breast-feeding; being on a diet during the last three month; renal disease; cancer; Fasting blood sugar more than 110; infection and inflammatory diseases

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Isfahan University of Medical Sciences

Street address

Hezarjarib street.Isfahan University of Medical Sciences

City

Isfahan

Postal code

Approval date

2015-12-21, 1394/09/30

Ethics committee reference number

IR.MUI.REC.1394.3.1051

Health conditions studied

1

Description of health condition studied

Hypertention

ICD-10 code

I10

ICD-10 code description

فشار خون بالا پرفشاری خون (شریانی) (خوش خیم) (ضروری)
(بدخیم) (اولیه) (سیستمیک)

2

Description of health condition studied

Dyslipidemia

ICD-10 code

E78.1

ICD-10 code description

هیپرکلیریدمی اندوزنیک

Primary outcomes

1

Description

Cholestrol

Timepoint

At the first and end of study

Method of measurement

laboratory

2

Description

HDL-C

Timepoint

At the first and end of study

Method of measurement

laboratory

3

Description

TG

Timepoint

AT THE FIRST AND THE END OF STUDY

Method of measurement

Laboratory measurements

4

Description

LDL-C

Timepoint

AT THE FIRST AND THE END OF STUDY

Method of measurement

Laboratory measurements

5

Description

blood pressure

Timepoint

first middle end of the study

Method of measurement

pressure indicator

6

Description

crp

Timepoint

first and end of the study

Method of measurement

Laboratory measurements

7

Description

weight

Timepoint

First,middle and the end of study

Method of measurement

scale

Secondary outcomes

empty

Intervention groups

1

Description

placebo: 12 gram sachet produced by Kamvar company,
Isfahan

Category

Placebo

2

Description

intervention: 36 gram flaxseed sachet

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinics affiliated with University of Medical Sciences

Full name of responsible person

Street address

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

School of Nutrition

Street address

Hezar jarib street

City

Isfahan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Isfahan University of Medical Sciences

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

Isfahan University of Medical Sciences- School of
Nutrition

Full name of responsible person

Naeme Haghighatsiar

Position

Masters student of nutrition

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Isfahan University of Medical Sciences- School of
Nutrition

Full name of responsible person

Gholamreza Askari

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PHD

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Naeme Haghighatsiar

Position

Masters student of nutrition

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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