

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

A clinical trial of the effects of flaxseed on blood pressure, Serum cholesterol and body mass index in patients with high blood pressure

Protocol summary

Summary

The study will be done in 2017 to evaluate the effects of flaxseed on the blood pressure, blood cholesterol level, and body mass index of hypertensive patients who are hospitalized in the Heart Clinic of Shohadaye Ashayer hospital, Khorramabad, Iran. 114 patients will be recruited through sequential non-random sampling and will be randomly allocated to three groups through block randomization. Eligibility criteria include: age between 35 to 70 years old, affliction by mild or moderate hypertension as diagnosed by a specialist, and no use of angiotensin converting enzyme inhibitors. Patients will be excluded if they develop diarrhea, inflammatory bowel disease, bowel obstruction, or allergy or need any kind of surgery during the course of the study. This is a three-group randomized clinical trial. Patients will be allocated to a 10-gram flaxseed, a 30-gram flaxseed, and a placebo (wheat flour) group. Blood pressure (primary outcome), body mass index, and blood cholesterol level (secondary outcomes) will be measured before, six and twelve weeks after the intervention. Razi Research Center will prepare three pack series of 10-gram flaxseed, 30-gram flaxseed, and wheat flour and will label them A, B, C, respectively. Patients will be asked to use the allocated pack after lunch for twelve weeks. At the end of each week, we will make telephone contacts with patients in order to assess their adherence to the treatments as well as the incidence of adverse effects of the treatments.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017030432865N1**

Registration date: **2017-06-18, 1396/03/28**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-06-18, 1396/03/28

Registrant information

Name

Massome Yarahmadi

Name of organization / entity

Lorestan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 916 967 2830

Email address

massomeyarahmadi@gmail.com

Recruitment status

Recruitment complete

Funding source

Research Administration of Lorestan University of Medical Sciences

Expected recruitment start date

2017-04-21, 1396/02/01

Expected recruitment end date

2018-03-19, 1396/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial of the effects of flaxseed on blood pressure, Serum cholesterol and body mass index in patients with high blood pressure

Public title

The effect of flaxseed on blood pressure

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age range 35 to 70 years;The risk of prehypertension 120/80 until the 139/89, mild hypertension 140/90 until the 159/99 and the average blood pressure of 160/100 until the 179/109, according to psychiatrists; Not having any allergy to flaxseed and its products; The lack of psychiatric disorders; Access patients or caregivers to phone; No pain and acute diseases; Access to the patient three months after entering the study; no use of angiotensin converting enzyme inhibitors such as captopril; Not taking digoxin; No history of obstructive pulmonary disease and inflammatory bowel, celiac disease, stomach ulcers, gastrointestinal bleeding, large, kidney failure Exclusion criteria: Unwillingness of patients or caregivers to continue research ; Diarrhea,inflammatory bowel disease, bowel obstruction, or allergy or need any kind of surgery during the course of the study; Having regular exercise and vigorous; The patient died; Out of reach of the patient's illness or change a contact number and responding to telephone follow; Pregnancy and lactation

Age

From **35 years** old to **70 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **114**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Lorestan University of Medical Sciences

Street address

Road Kamalvand, KHorramabad,Lorestan,Iran

City

KHorramabad

Postal code

Approval date

2017-02-20, 1395/12/02

Ethics committee reference number

lums.rec.1395.194

Health conditions studied

1

Description of health condition studied

Hypertension

ICD-10 code

I10-I15

ICD-10 code description

Hypertensive diseases

Primary outcomes

1

Description

Blood pressure

Timepoint

Before and six and twelve weeks after the intervention

Method of measurement

Mark Hine sphygmomanometer

Secondary outcomes

1

Description

Body mass index

Timepoint

Before and six and twelve weeks after the intervention

Method of measurement

Through dividing body weight (kg) by height (m*2)

2

Description

Blood cholesterol level

Timepoint

Before and six and twelve weeks after the intervention

Method of measurement

Laboratory tests

Intervention groups

1

Description

intervention group 1: 10 g of powder flaxseed daily after meals for 12 weeks

Category

Treatment - Drugs

2

Description

intervention group 2: 30 grams of powdered flaxseed daily after meals for 12 weeks

Category

Treatment - Drugs

3**Description**

Control group: daily 10 grams of wheat flour for 12 weeks

Category

Treatment - Drugs

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

The Heart Clinic of Shohaday-e Ashayer Hospital, Khorramabad, Iran

Full name of responsible person

Massome Yarahmadi

Street address

Enghelab st. Khorramabad, Lorestan, Iran

City

Khorramabad

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

Vice President of Research Lorestan University of Medical Sciences

Full name of responsible person

Mojgan KHademi

Street address

Kamalvand Road, Khorramabad

City

Khorramabad

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice President of Research Lorestan 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**

Lorestan University of Medical Sciences

Full name of responsible person

Massome Yarahmadi

Position

Nursing Graduate Student

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

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

Lorestan University of Medical Sciences

Full name of responsible person

Tahere Toulabi

Position

Phd Nursing

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

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Lorestan University Of Medical Sciences

Full name of responsible person

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Position

Four Semester Nursing

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Fax**Email**

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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