Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
Eram Intersection, Western Goldasht Street, KHoramabad
City
KHoramabad
Postal code
6814765134
Phone
+98 66 3342 9183
Fax
Email
massomeyarahmadi@gmail.com
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
Lorestan University of Medical Sciences, School of Nursing and Midwifery, Nursing
City
Khorramabad
Postal code
381351698
Phone
+98 66 3620 0140
Fax
Email
toulabi_t@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Lorestan University Of Medical Sciences
Full name of responsible person
Massome Yarahmadi
Position
Four Semester Nursing
Other areas of specialty/work
Street address
Street Eram, Western Goldasht, Khorramabad, Lorestan

City
KHorramabad
Postal code
6814765134
Phone
+98 664218030
Fax
Email
massomeyarahmadi@gmail.com
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