Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of breads containing flaxseed and sesame on the blood pressure of patients with stage I hypertension

Protocol summary

Summary

The purpose of this study is to compare the effect of daily intake of breads containing flaxseed or sesame powder on the blood pressure of individuals with stage I hypertension. This is a randomized, single centered, and single blinded study. Researchers and analyzers are not aware of the type of bread that is used by patients. Eligible subjects will be selected from the patients attending the Yazd Cardiovascular Research Center. Main inclusion criteria are ages between 30 to 65 years, and having stage I hypertension. Pregnant and diabetic patients or individuals suffering from severe systemic or intestinal diseases will be excluded. Total sample size is 84 with at least 42 patients in each group. Groups A and B will receive daily breads containing 30 grams of either flaxseed or sesame powder, respectively. Study will be started on May 21st of 2016 and will last for 14 weeks. Measured outcomes are changes in systolic and diastolic blood pressure. After initial blood taking, patients will be instructed to get their weekly breads from a collaborative store. To be sure that breads are used properly, patients will be contacted either face to face or by phone and ask about how they are taking their breads and how many are left. Systolic and diastolic blood pressure will be measured at the beginning, middle and at the end of the study. Eating habits and physical activities will also be asked at these times.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016050327729N1**
Registration date: **2016-05-23, 1395/03/03**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-05-23, 1395/03/03

Registrant information

Name

Moneyreh Modares Mosadegh

Name of organization / entity

Shahid Sadoughi University of Medical Sciences

Country

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Phone

+98 35 3820 3419

Email address

modares@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Sadoughi University of Medical Sciences

Expected recruitment start date

2016-05-21, 1395/03/01

Expected recruitment end date

2016-09-05, 1395/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of breads containing flaxseed and sesame on the blood pressure of patients with stage I hypertension

Public title

Comparison of breads containing flaxseed and sesame on the blood pressure of patients with mild to moderate hypertension

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age between 30 to 65 years; stage I hypertension (Systolic Blood Pressure (SBP) 140-159 mmHg, Diastolic Blood Pressure (DBP) 90-99 mmHg) using prevailed treatment; using a particular anti-hypertensive therapy for at least 3 months and Exclusion Criteria: pregnant women or women planning to get pregnant; being allergic to sesame or flaxseed; suffering from intestinal diseases such as Crohn's disease, colitis, peptic ulcer, irritable bowel syndrome (IBS), and other severe systemic diseases like systemic lupus erythematosus (SLE), cancer, or stage IV respiratory diseases; history of myocardial infarction; coronary bypass surgery during last 6 months; stage II hypertension; diabetic patients; routinely using nonsteroidal anti-inflammatory drugs (NSAID's); change of antihypertensive drugs during the study

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: **84**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical Committee of Medical School Of Shahid Sadoughi University of Medical sciences

Street address

Third floor, Centeral Building, Bahonar Square

City

Yazd

Postal code

Approval date

2016-03-14, 1394/12/24

Ethics committee reference number

IR.SSU.MEDICINE.REC.1394.492

Health conditions studied

1

Description of health condition studied

Hypertension

ICD-10 code

I10

ICD-10 code description

Essential (primary) hypertension

Primary outcomes

1

Description

systolic blood pressure

Timepoint

prior to study, Seventh week, and at the end of study

Method of measurement

in mmHg using mercuric manometer

2

Description

Diastolic blood pressure

Timepoint

prior to study, Seventh week, and at the end of study

Method of measurement

in mmHg using mercuric manometer

Secondary outcomes

1

Description

Body Mass Index (BMI)

Timepoint

prior to study, Seventh week, and at the end of study

Method of measurement

kg/m^2 ; it is calculated measuring weight in kilogram and height in meter

Intervention groups

1

Description

Patients in group A will receive 30 grams of powdered flaxseed by using 90 gram bread daily

Category

Treatment - Other

2

Description

Patients in group B will receive 30 grams of powdered sesame by using 90 gram bread daily

Category

Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Yazd Cardiovascular Research Center
Full name of responsible person
Dr. Hadiani
Street address
Afshar hospital, Jomhuri Islami Blvd.
City
Yazd

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for Research and Technology of Shahid Sadoughi University of Medical Sciences
Full name of responsible person
Dr. Mehrparvar
Street address
Third floor, Centeral Building, Bahonar Square
City
Yazd
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for Research and Technology of Shahid Sadoughi 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
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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