Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effects of flaxseed and sesame powder on the antioxidant activity and blood profile of patients with stage I hypertension

Protocol summary

Summary

The purpose of this study is to compare the antioxidant activity and changes in the lipid profile of hypertensive individuals taking 30 grams of either flaxseed or sesame powder daily. This is a randomized, single centered, and single blinded study. Researchers and analyzers are not aware of the type of bread that is eaten by patients. Eligible patients will be selected from the patients attending the Yazd Cardiovascular Research Center. Main inclusion criteria are ages between 30 to 65 years, having stage I hypertension, and cholesterol level below 240 mg/dL. Patients using drugs for hyperlipidemia, pregnant patients, or individuals suffering from severe systemic or intestinal diseases, diabetes, or myocardial infarction will be excluded. Total sample size is 90 with at least 45 patients in each group. Patients will be allocated to two groups using blocked randomization block sizes of four. Groups A and B will receive 90 grams of bread containing 30 grams of either flaxseed or sesame powder for 14 weeks, respectively. Measured outcomes include, free radical scavenging capacity, malondialdehyde (MDA), cholesterol, triglyceride, LDL, and HDL. These parameters will be measured at the beginning, middle and end of the study. Questions about eating habits and physical activities will also be asked at these times. After initial blood taking, patients will be instructed to get their weekly breads from a particular store. To be sure patients consumed their breads properly; they will be regularly contacted either face to face or by phone.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016050727729N2**

Registration date: **2016-05-28, 1395/03/08**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-05-28, 1395/03/08

Registrant information

Name

Moneyreh Modares Mosadegh

Name of organization / entity

Shahid Sadoughi University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Shahid Sadoughi University of Medical Sciences

Expected recruitment start date

2016-05-28, 1395/03/08

Expected recruitment end date

2016-09-12, 1395/06/22

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of flaxseed and sesame powder on the antioxidant activity and blood profile of patients with stage I hypertension

Public title
Comparison of the effects of flaxseed and sesame powder on the antioxidant activity and blood profile 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 a particular anti-hypertensive therapy for at least 3 months; cholesterol less than 240 mg/dl. 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 such as systemic lupus erythematosus (SLE), cancer, or stage IV respiratory diseases; history of myocardial infarction; coronary bypass surgery during last 6 months; stage II hypertension; diabetes; routinely using nonsteroidal anti-inflammatory drugs (NSAID's); change of anti-hypertensive drugs during the study; using drugs for hyperlipidemia
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)
Single 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 sciences
Street address
Alem square
City
Yazd
Postal code
8915173149
Approval date
2016-03-02, 1394/12/12
Ethics committee reference number
IR.SSU.REC.1394.227

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
free radical scavenging capacity
Timepoint
prior to study, Seventh week, and at the end of study
Method of measurement
this is showed in % and is obtained by measuring DPPH (1,1-diphenyl-2-picryl hydrazyl radical). This measurement is done by Elisa

2

Description
malondialdehyde (MDA)
Timepoint
prior to study, Seventh week, and at the end of study
Method of measurement
micromol/L; it is measured by Elisa

3

Description
cholesterol
Timepoint
prior to study, Seventh week, and at the end of study
Method of measurement
mg/dL

4

Description
triglyceride
Timepoint
prior to study, Seventh week, and at the end of study
Method of measurement
mg/dL

5

Description
low density lipoprotein (LDL)
Timepoint

prior to study, Seventh week, and at the end of study
Method of measurement
mg/dL

6

Description
High density lipoprotein (HDL)
Timepoint
prior to study, Seventh week, and at the end of study
Method of measurement
mg/dL

Secondary outcomes

empty

Intervention groups

1

Description
Group A receives 30 grams of powdered flaxseed by eating 90 gram bread daily for 14 weeks
Category
Treatment - Other

2

Description
Group B receives 30 grams of of powdered sesame by eating 90 gram bread daily for 14 weeks
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Yazd Cardiovascular Research Center
Full name of responsible person
Dr. Namayandeh
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
Name of organization / entity
Shahid Sadoughi University of Medical Sciences
Full name of responsible person
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Person responsible for updating data

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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