

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 May 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

Country

Iran (Islamic Republic of)

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

2016-05-28, 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, Central 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

Moneyreh Modares Mosadegh

Position

Faculty of Dept. of Pharmacology/ Pharm.D.

Other areas of specialty/work

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Web page address**Person responsible for updating data****Contact****Name of organization / entity**

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Full name of responsible person

Moneyreh Modares Mosadeg

Position

Faculty of Dept. of Pharmacology/ Pharm.D.

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

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City

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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