Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Study of the effect of bread containing flaxseed on patients with metabolic syndrome

Protocol summary

Study aim
Determination of the effect or bread containing Flaxseed on patients with metabolic syndrome

Design
48 metabolic syndrome patients are randomly divided in two equal groups clinical trial parallel two blind

Settings and conduct
patients with metabolic syndrome from Kashani Hospital were randomly divided into two groups. The rate of lipid profile, , BMI,wight ,waist circumference, blood pressure, FBS, and height were measured. In the intervention group, two units of 20% flaxseed bread and the control group intake 2 simple breads. And after 6 weeks the blood sampling will be done again

Participants/Inclusion and exclusion criteria
Inclusion criteria: study Having 3 Indices of 5 Metabolic Syndrome Indicators: Waist circumference is more than 102 centimeters for men and more than 88 centimeters for women, The level of triglyceride is greater than or equal to 150 mg / dL, HDL cholesterol levels less than 40 for men and less than 50 mg per decilitre for women, The fasting blood sugar level is greater than or equal to 100 mg / dL, The blood pressure is greater than or equal to 130/85 mmHg , Men and women 20-50 years old, Patients who agree to participate in the study. Condition of failure to enter: Tobacco use, Consumption of flax seed bread in the last 6 months ,Pregnancy, breast feeding, menopause Exclusion criteria: The incidence of diseases or the use of drugs that affect metabolic indexes, The incidence of gastrointestinal diseases during the research so that the continuation of the research is not possible, Pregnancy during the project, Chang in types or doses of drugs, Participants do not cooperate in different stages of the study

Intervention groups
1- The intervention group: received 2 unit flax seed bread 20% 2- The control group: receives 2 units of bread containing 100 grams of wheat

Main outcome variables
Triglyceride، HDL، FBS ، blood pressure ، waist circumference

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180305038966N2**
Registration date: **2018-08-18, 1397/05/27**
Registration timing: **retrospective**

Last update: **2022-11-03, 1401/08/12**
Update count: **1**

Registration date
2018-08-18, 1397/05/27

Registrant information

Name
Nahid Shakeri

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 4486 1815

Email address
nutrition@mail.mui.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-07-16, 1397/04/25

Expected recruitment end date
2018-08-08, 1397/05/17

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Study of the effect of bread containing flaxseed on patients with metabolic syndrome

Public title
Study of the effect of bread containing flaxseed on patients with metabolic syndrome

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Having 3 Indices of 5 Metabolic Syndrome Indicators. Waist circumference is more than 102 centimeters for men and more than 88 centimeters for women. The level of triglyceride is greater than or equal to 150 mg / dL. HDL cholesterol levels less than 40 for men and less than 50 mg per decilitre for women. The fasting blood sugar level is greater than or equal to 100 mg / dL. The blood pressure is greater than or equal to 130/85 mmHg Men and wemen 20-50 years old Patients who agree to participate in the study

Exclusion criteria:
Tobacco use - Adherence to a particular diet - Consumption bread of flaxseed in the last 6 months - Pregnancy, breast feeding, menopause

Age
From **20 years** old to **50 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **48**

Randomization (investigator's opinion)
Randomized

Randomization description
The 48 patients selected are divided into two groups of intervention and placebo. In the present study, a simple randomization method will be used, the randomization unit will be used individually and we will use the random number table method to generate random sequences. A random number table is a massive set of numbers that is generated without a definite pattern and completely randomized. The next step is to hide random assignments and use non-transparent sealed envelopes with random sequences. will be. Then, based on the sample size of the study, a number of envelopes with an aluminum wrapper are prepared and each random sequence created on a card is recorded and the cards are inserted into the envelopes respectively. At the time of the registration of the participants, According to the order of entry of eligible participants of the study, one of the envelopes is opened in sequence and the participant's group is revealed

Blinding (investigator's opinion)
Double blinded

Blinding description
researchers and patients are unaware of the type of bread they are being divided

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee Science and Research Tehran

Street address
میدان دانشگاه، بلوار شهدای حصارک

City
Tehran

Province
Tehran

Postal code
1477893855

Approval date
2018-02-18, 1396/11/29

Ethics committee reference number
IR.IAU.SRB.REC.1396.100

Health conditions studied

1

Description of health condition studied
Metabolic syndrome

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Serum level of triglyceride

Timepoint
At the beginning of the study and the end of the sixth week

Method of measurement
By enzyme- mg/dl

2

Description
Serum level of HDL

Timepoint
At the beginning of the study and the end of the sixth week

Method of measurement
By enzyme- mg/dl

3

Description
Serum level of FBS
Timepoint
At the beginning of the study and the end of the sixth week
Method of measurement
By enzyme- mg/dl

4

Description
Blood pressure
Timepoint
At the beginning of the study and the end of the sixth week
Method of measurement
Digital Manometer mmHg

5

Description
Waist
Timepoint
At the beginning of the study and the end of the sixth week
Method of measurement
Strip Meter- Centimeters

6

Description
Body mass index
Timepoint
At the beginning of the study and the end of the sixth week
Method of measurement
Formula weight/ High2

7

Description
Physical activity
Timepoint
Initially,the middle and end of the sixth week study
Method of measurement
Met questionnaire

8

Description
Food intake
Timepoint
Initially,the middle and end of the sixth week study
Method of measurement
Food frequency questionnaire 3 days

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: intake 2 unit of bread containing 20 gram of flax seed flour and 80 gram of wheat flour for 6 weeks and twice a day
Category
Treatment - Other

2

Description
Control group: intake 2 unit of simple bread containing 100 gram of wheat flour for 6 weeks and twice a day
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Kashni hospital and patients referred to other hospitals and private clinics in isfahan
Full name of responsible person
Nahid Shakeri
Street address
Kashani Ave, Kashani hospital
City
Isfahan
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Isfehan
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8183983434
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nutrition@mail.mui.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kashani Hospital
Full name of responsible person
Nahid Shakeri
Street address
Kashani Ave, Kashani Hospital
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Postal code

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Phone
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Email
nutrition@mail.mui.ac.ir

Grant name
It is not done at the university and it is not a credit for the university

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Kashani Hospital

Proportion provided by this source
1

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Other

Person responsible for general inquiries

Contact

Name of organization / entity
Islamic Azad University

Full name of responsible person
Nahid Shakeri

Position
Master nutrition

Latest degree
Master

Other areas of specialty/work
Nutrition

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
NahidShakeri

Position
University staff

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Person responsible for updating data

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Nahid Shakeri

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to

make this available	
Data Dictionary	Undecided - It is not yet known if there will be a plan to make this available