

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Study of the Effect of bread containing flaxseed on serum level of Apelin and lipid profile in hyperlipidemic patients

Protocol summary

Study aim

Determination of the effect of bread containing flaxseed on serum level of Apelin and lipid profile in hyperlipidemic patients to prevent cardiovascular diseases

Design

48 hyper lipidemic patients are randomly divided in two equal groups clinical trial parallel two blind(researcher and patients)

Settings and conduct

patients from Kashani Hospital were randomly divided into two groups. The rate of lipid profile, Apelin, BMI, weight, waist circumference 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: High is one of the lipid factors: cholesterol is greater than or equal to 200, triglycerides greater or equal. LDL is greater or equal 130 and rate of HDL is less than 40 for men and 50 mg per deciliter for women (high levels of LDL or cholesterol are essential Men and women 20-50 years old Patients who agree to participate in the study Condition of failure to enter: 1- Tobacco use 2- Adherence to particular diet 3- Consumption of flax seed bread in the last 6 months 4- Pregnancy, breast feeding, menopause Exclusion criteria: Incidence of certain diseases, such as diabetes, hypothyroidism, renal failure, cholestasis or the use of drugs such as corticosteroids that affect blood lipids or the occurrence of gastrointestinal diseases during research, so that further research is not possible Pregnancy during the project Change in type or dose of anti hyperlipidemia drugs or drugs that affect blood lipids 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

Cholesterol, triglyceride, Apelin, HDL, LDL

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180305038966N1**

Registration date: **2018-03-29, 1397/01/09**

Registration timing: **retrospective**

Last update: **2018-03-29, 1397/01/09**

Update count: **0**

Registration date

2018-03-29, 1397/01/09

Registrant information

Name

Nahid Shakeri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4486 1815

Email address

nutrition@mail.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-28, 1396/11/08

Expected recruitment end date

2018-03-28, 1397/01/08

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 serum level of Apelin and lipid profile in hyperlipidemic patients

Public title
Study of the Effect of bread containing flaxseed on serum level of Apelin and lipid profile in hyperlipidemic patients

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
high is one of the lipid factors: cholesterol is grater than or equal to 200.triglycerides grater or equal. LDL is grater or equal 130 and rate of HDL is less than 40 for men and 50 mg per deciliter for women(high levels of LDL or cholesterol are essential 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
48 patients are randomly assigned to two equal groups (lottery) of intervention and placebo

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 of Science and Research Tehran
Street address
Shahid hesarak Bivd, university Square
City
Tehran
Province
Tehran
Postal code
1477893855
Approval date
2018-02-19, 1396/11/30
Ethics committee reference number
IR.IAU.SRB.REC.1396.100

Health conditions studied

1

Description of health condition studied
Hyperlipidemia
ICD-10 code
E78
ICD-10 code description
Disorders of lipoprotein metabolism and other lipidemias

Primary outcomes

1

Description
serum level of LDL
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 total cholesterol
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 Apelin
Timepoint
At the beginning of the study and the end of the sixth week
Method of measurement
Eliza_ picogram/ml

4

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

5

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

6

Description

Blood pressure

Timepoint

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

Method of measurement

Digital Manometer mmHg

7

Description

Body mass index

Timepoint

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

Method of measurement

Formula weight/High²

8

Description

Physical activity

Timepoint

Initially, the middle and end of the sixth week study

Method of measurement

Met questionnaire

9

Description

Food intake

Timepoint

Initially, the middle and end of the sixth week study

Method of measurement

Food frequency questionnaire 3 days

10

Description

Waist

Timepoint

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

week

Method of measurement

Strip Meter- centimeters

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

Prevention

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

Province

Isfahan

Postal code

8183983434

Phone

+98 31 3233 0091

Email

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 , Kashni Hospital

City

Isfahan
Province
Isfahan
Postal code
8183983434
Phone
+98 31 3233 0091
Email
nutrition@mail.mui.ac.ir
Grant name
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
Public
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 student nutrition
Latest degree
Bachelor
Other areas of specialty/work
Nutrition
Street address
Shahid Hesarak B lvd , University square
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Province
Tehran
Postal code
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Mohammad Hasan Entezari

Position
Philosophy Doctor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Hezarjarib Ave, Isfahan University of MedicalSciences
City
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Isfahan
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8174673461
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Email
entezari@hlth.mui.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Islamic Azad University
Full name of responsible person
Nahid Shakeri
Position
Student master nutrition
Latest degree
Bachelor
Other areas of specialty/work
Nutrition
Street address
Shahid Hesarak Blvd, University Square
City
Tehran
Province
Tehran
Postal code
1477893855
Phone
+98 21 4486 1815
Email
nutrition@mail.mui.ac.ir

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