Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation the effect of the fenugreek hydrolyzed protein on lipids and CRP levels in hypercholesterolemia patients

Protocol summary

Study aim
Determination of mean lipid profile, hs-CRP inflammatory marker, fasting blood sugar, blood pressure and body mass index in hypercholesterolemia patients receiving hydrolyzed fenugreek protein and placebo

Design
A controlled clinical trial with parallel groups, double-blind, randomized, phase 3 on 60 patients, using free online random allocation software for randomization.

Settings and conduct
This study will be performed in Isfahan Chamran hospital. Sixty hypercholesterolemia patients will be selected based on inclusion and exclusion criteria and will be divided into two groups of 30 intervention and placebo. Patients will take medication 40 mg daily for 2 months. Patients will be advised to change their lifestyle. At the beginning and end of study, lipid profile, hs-CRP inflammatory marker, fasting blood sugar, blood pressure and body mass index will be measured and compared. Participants and evaluators will be blind to the outcome. The appearance of the both types of capsules will be similar and only the researcher will know about the assignment of patients to groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: aged 18-65 years; LDL blood levels between 116 -180 mg / dL. Exclusion criteria: systemic underlying disease; sensitivity to intervention medication.

Intervention groups
Intervention group: fenugreek hydrolyzed protein. Control group: similar capsule filled by placebo.

Main outcome variables
Lipid profile؛ hs-CRP inflammatory marker؛ fasting blood sugar؛ blood pressure؛ body mass index

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210125050142N1**
Registration date: **2021-03-11, 1399/12/21**
Registration timing: **prospective**

Last update: **2021-03-11, 1399/12/21**
Update count: **0**

Registration date
2021-03-11, 1399/12/21

Registrant information

Name
Mahdi Badiee Gavarti

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-04-04, 1400/01/15

Expected recruitment end date
2021-06-20, 1400/03/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation the effect of the fenugreek hydrolyzed protein on lipids and CRP levels in hypercholesterolemia patients

Public title

Evaluation the effect of fenugreek on reducing blood lipids

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with low to moderate risk for cardiovascular events LDL 116 -180 mg /dL

Exclusion criteria:

Drinking alcohol, Use of effective supplements on blood lipids (such as fish oil), Immunosuppressive drugs, blood lipid-lowering drugs (statins, fibrates, niacin, ...) People with hypothyroidism, nephrotic syndrome or renal dysfunction or liver dysfunction People with uncontrolled hypertension (systolic blood pressure greater than 160 or diastolic blood pressure greater than 100 mmHg), History of dizziness and convulsions, Pregnancy or lactation Sensitivity to studied plant

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

First, it determines a total sample size, then randomly assigns a set of them to groups A and group B, which is executed by random allocation software, which produces a sequence of random numbers with the intended code. The output list of random numbers is printed. Then, based on the sample size of the research, a number of envelopes are prepared and each of the random sequences created is registered on a card and the cards are placed inside the envelopes in order. In order to maintain a random sequence, envelopes are numbered in the same way on the outer surface. Finally, the lids of the envelopes are glued and placed in a box, respectively. At the beginning of the registration of participants, one of the envelopes of the letter is opened and the assigned group of the participant is revealed according to the order of entry of the eligible participants.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is double-blind. Both participants and outcome assessors are unaware of the type of intervention received, but patients will be explained how to implement the plan and whether they are randomly assigned to one of these two groups. The size, color and design of the drug under study and the placebo prescribed in the two groups are quite similar. The lead researcher determines the drug codes and the participants and evaluators of the project are not aware of the type of drugs received.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

ethics committee of the National Institute for medical research development

Street address

No. 21, beginning of Besat St., West Fatemi St., Tehran

City

Tehran

Province

Tehran

Postal code

۱۴۱۹۶۹۳۱۱۱

Approval date

2020-01-14, 1398/10/24

Ethics committee reference number

IR.NIMAD.REC.1398.402

Health conditions studied

1

Description of health condition studied

Hypercholesterolemia

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Mean of Total Cholesterol

Timepoint

Before the intervention and 2 months after the intervention

Method of measurement

Blood level mg mg / dL by laboratory

2

Description

Mean of High-Density Lipoprotein

Timepoint

Before the intervention and 2 months after the intervention

Method of measurement

Blood level mg mg / dL by laboratory

3

Description

Mean of Low-Density Lipoprotein

Timepoint

Before the intervention and 2 months after the intervention

Method of measurement

Blood level mg mg / dL by laboratory

4

Description

Mean of Triglyceride

Timepoint

Before the intervention and 2 months after the intervention

Method of measurement

Blood level mg mg / dL by laboratory

5

Description

Mean of high-sensitivity C-reactive protein

Timepoint

Before the intervention and 2 months after the intervention

Method of measurement

Blood level mg mg / dL by laboratory

Secondary outcomes

1

Description

Mean of fasting blood sugar

Timepoint

Before the intervention and 2 months after the intervention

Method of measurement

Blood level mg mg / dL by laboratory

2

Description

Mean of blood pressure

Timepoint

Before the intervention and 2 months after the intervention

Method of measurement

Blood pressure monitor

3

Description

Mean of body mass index

Timepoint

Before the intervention and 2 months after the intervention

Method of measurement

Tape meters, digital scales and calculation formulas

Intervention groups

1

Description

Intervention group: Patients in this group will be prescribed a 40 gram capsule of fenugreek hydrolyzed protein daily for 2 months. Lipid profile, hs-CRP level, fasting blood sugar, blood pressure and body mass index will be measured before the intervention and after 2 months of follow-up when the patient taking the prescribed drug.

Category

Treatment - Drugs

2

Description

Control group: Patients in this group will be prescribed a 40-gram placebo capsule, which is similar in appearance and packaging to the main drug under study, daily for 2 months. Lipid profile, hs-CRP level, fasting blood sugar, blood pressure and body mass index will be measured before the intervention and after 2 months of follow-up when the patient is taking the prescribed drug.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Chamran hospital

Full name of responsible person

Masoumeh Sadeghi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name

Grant code / Reference number

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

Title of funding source
National institute for medical research development

Proportion provided by this source
100

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
Esfahan University of Medical Sciences

Full name of responsible person
Mahdi Badiee Gavarti

Position
Medical student

Latest degree
A Level or less

Other areas of specialty/work
General Practitioner

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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