

# 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 Badiie Gavarti

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3577 0701

##### Email address

mbadieeg@res.mui.ac.ir

#### 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

**Street address**

2nd Moshtagh St, Isfahan

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**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

National institute for medical research development

**Full name of responsible person**

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No. 21, Besat St., beginning of West Fatemi St.,  
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**Province**

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NIMAD@RESEARCH.AC.IR

**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 Badiie Gavarti

**Position**

Medical student

**Latest degree**

A Level or less

**Other areas of specialty/work**

General Practitioner

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## Person responsible for scientific inquiries

**Contact**

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**Full name of responsible person**

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Research Professor of Cardiology

**Latest degree**

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## Person responsible for updating data

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Mahdi Badiie Gavarti

**Position**

Medical student

**Latest degree**

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**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