

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effect of dietary Fenugreek seed powder on serum lipid profiles in patients with hyperlipidemia.

Protocol summary

Summary

We studied the effect of 2 months of oral administration of powdered fenugreek seeds on blood lipid profile. In this study, 40 patients (20 intervention and 20 controls) with hyperlipidemia in the clinical spectrum of not consumption of lipid-lowering drugs will randomly selected for the study. inclusion criteria :Samples older than 18 and younger than 65 years old were associated with fat; LDL between 160 and 189 in healthy individuals or patient with one risk factors; LDL between 130 and 159 for those with two or more risk factors. exclusion criteria: having an underlying disease such as diabetes, IHD, hypertension, metabolic syndrome, peripheral vascular disease, coronary artery disease and ... ; LDL more than 190 that patients need medical treatment (for healthy people or individuals with one risk factor); LDL $\geq$ 160 in patient that need drug treatment (for those with two or more risk factors). in intervention Group each patient receive 5 grams of powdered fenugreek seeds daily for two months, with recommendations for lifestyle changes and a control group receiving only recommendations. After two months blood examining for all of the patients is compared to the prior.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013111815452N1**

Registration date: **2014-01-19, 1392/10/29**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-01-19, 1392/10/29

Registrant information

Name

Elahe Yousefi

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Qazvin University of Medical Sciences

Expected recruitment start date

2014-01-20, 1392/10/30

Expected recruitment end date

2014-03-20, 1392/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of dietary Fenugreek seed powder on serum lipid profiles in patients with hyperlipidemia.

Public title

TF effects on blood lipids

Purpose

Prevention

Inclusion/Exclusion criteria

The inclusion criteria: up to 18 years and less than 65 years old; an experiment with one of the following factors related to lipid LDL > 135 mg / dl; HDL < 40 mg / dl; Chol > 200 mg / dl; TG > 150 mg / dl. The exclusion criteria having underlying diseases such as diabetes, IHD, hypertension, metabolic syndrome, peripheral

vascular disease, coronary artery disease and ...; LDL more than 190 in patients that need of medical treatment (for healthy people or with one risk factor); LDL $\geq$ 160 in patient that need drug treatment (for those with two or more risk factors). Risk Factors: 1 - Smoking 2 - hypertension 3 - low HDL level (less than 40) 4 - history of coronary artery disease at an early age in the household (less than 55 years in males and in females under age 65years old) 5 - Age above 65 years. important point: diabetes mellitus, peripheral vascular disease and coronary artery disease are considered equivalent whit CAD. (CAD equivalent)

Age

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

Gender

Both

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Qazvin University of Medical Science

Street address

above the Dadgostary junction, Qazvin University of Medical Science

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Postal code

Approval date

2013-07-15, 1392/04/24

Ethics committee reference number

5959/20/3

Health conditions studied

1

Description of health condition studied

Hyperlipidaemia

ICD-10 code

E78.5

ICD-10 code description

Hyperlipidaemia, unspecified

Primary outcomes

1

Description

serum lipid

Timepoint

in the begining of study and then after 2 month from the begining

Method of measurement

blood exam mg/dl

Secondary outcomes

empty

Intervention groups

1

Description

in intevention Group each patient receive 5 grams of powdered fenugreek seeds daily for two months, with recommendations for lifestyle changes along this period.

Category

Treatment - Drugs

2

Description

control Group only receive recommendations for lifestyle changes for two months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital

Full name of responsible person

Katayon Ziari

Street address

Basij Highway, Besat Hospital

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

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

Qazvin 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**

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Web page address**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