

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

effect of fenugreek seeds on serum irisin level, glucose metabolism and lipid profile in diabetes type 2

Protocol summary

Summary

study aim: to determine the effect of fenugreek seeds on serum irisin level, glucose metabolism and lipid profile in diabetes type 2 study design: Randomized, controlled, no blinding, no placebo, single-center, parallel study Methods: A) study population: Inclusion criteria: voluntary participation; At least 1 year and a maximum of 10 years diabetes history and observing at least 6 months diabetic diet; taking oral drugs lowering blood glucose to control diabetes; 18 to 65 years old; Lack of pregnancy and lactation; Not having certain diseases (liver, kidney, heart, thyroid, rheumatoid, respiratory, metabolic, gastrointestinal, malignancy, allergic diseases); no need for insulin; not using dietary, vitamin and mineral supplements, at least three months before the study; not hormone therapy; no smoking; no using other medicinal plants routinely, at least 3 months prior to the study exclusion criteria: unwillingness to continue; developing specific diseases (liver, kidney, heart, thyroid, rheumatoid, respiratory, metabolic, gastrointestinal, malignancy, allergic diseases) during the study; starting pregnancy and lactation; starting insulin therapy; starting using dietary, vitamin and mineral supplements; change in the dose of oral blood glucose lowering drugs; Change in the physical activity during the study; start taking other medicinal plants routinely B) study intervention: 15 grams of powdered fenugreek seeds in doses of 5 grams three times a day between meals, dissolved in water C) duration of intervention: 8 weeks D)study outcomes: FBS, 2hPPG ,HbA1c , fastin insulin, HOMA-IR , HOMA-B , QUICKI irisin T-chol, LDL, HDL, TG, VLDL

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017013032294N1**

Registration date: **2017-03-07, 1395/12/17**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-03-07, 1395/12/17

Registrant information

Name

Rahele Tavakoly

Name of organization / entity

Isfahan University of Medical sciences

Country

Iran (Islamic Republic of)

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+98 31 3668 8487

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Recruitment status

Recruitment complete

Funding source

School of Nutrition and Food Sciences, Isfahan University of Medical Sciences

Expected recruitment start date

2017-03-20, 1395/12/30

Expected recruitment end date

2017-06-20, 1396/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

effect of fenugreek seeds on serum irisin level, glucose metabolism and lipid profile in diabetes type 2

Public title

effect of fenugreek in the treatment of diabetes

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: voluntary participation; At least 1 year and a maximum of 10 years diabetes history and observing at least 6 months diabetic diet; taking oral drugs lowering blood glucose to control diabetes; 18 to 65 years old; Lack of pregnancy and lactation; Not having certain diseases (liver, kidney, heart, thyroid, rheumatoid, respiratory, metabolic, gastrointestinal, malignancy, allergic diseases); no need for insulin; not using dietary, vitamin and mineral supplements, at least three months before the study; not hormone therapy; no smoking; no using other medicinal plants routinely, at least 3 months prior to the study exclusion criteria: unwillingness to continue; developing specific diseases (liver, kidney, heart, thyroid, rheumatoid, respiratory, metabolic, gastrointestinal, malignancy, allergic diseases) during the study; starting pregnancy and lactation; starting insulin therapy; starting using dietary, vitamin and mineral supplements; change in the dose of oral blood glucose lowering drugs; Change in the physical activity during the study; start taking other medicinal plants routinely

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

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **48**

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
Isfahan University of Medical Sciences
Street address
Hezar Jirib st.
City
Isfahan

Postal code
Approval date
2016-06-26, 1395/04/06
Ethics committee reference number
IR.MUI.REC.1395.3.225

Health conditions studied

1

Description of health condition studied
diabetes
ICD-10 code
E11
ICD-10 code description
Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description
HDL
Timepoint
before intervention and 2 months after starting the intervention
Method of measurement
Measurement of serum level

2

Description
LDL
Timepoint
before intervention and 2 months after starting the intervention
Method of measurement
Measurement of serum level

3

Description
total cholesterol
Timepoint
before intervention and 2 months after starting the intervention
Method of measurement
Measurement of serum level

4

Description
triglyceride
Timepoint
before intervention and 2 months after starting the intervention
Method of measurement
Measurement of serum level

5

Description

irisin

Timepoint

before intervention and 2 months after starting the intervention

Method of measurement

Measurement of serum level by ELISA kit

6

Description

fasting glucose

Timepoint

before intervention and 2 months after starting the intervention

Method of measurement

Measurement of serum level

7

Description

2hppg

Timepoint

before intervention and 2 months after starting the intervention

Method of measurement

Measurement of serum level

8

Description

HbA1C

Timepoint

before intervention and 2 months after starting the intervention

Method of measurement

Measurement of blood level

9

Description

insulin

Timepoint

before intervention and 2 months after starting the intervention

Method of measurement

Measurement of serum level by ELISA kit

10

Description

VLDL

Timepoint

before intervention and 2 months after starting the intervention

Method of measurement

formula calculation

Secondary outcomes

1

Description

HOMA-IR

Timepoint

before intervention and 2 months after starting the intervention

Method of measurement

formula calculation

2

Description

HOMA-B

Timepoint

before intervention and 2 months after starting the intervention

Method of measurement

formula calculation

3

Description

QUICKI

Timepoint

before intervention and 2 months after starting the intervention

Method of measurement

formula calculation

Intervention groups

1

Description

intervention group: 15 grams of powdered fenugreek seeds in doses of 5 grams three times a day between meals, dissolved in water for 8 weeks

Category

Treatment - Other

2

Description

control group: no action

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Endocrinology and Metabolism Research Center,
Isfahan University of Medical Sciences

Full name of responsible person

Ashraf Aminorroaya

Street address

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Mohammad Hassan Entezari

Street address

Hezar Jirib st.

City

Isfahan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Isfahan 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

School of Nutrition and Food Sciences, Isfahan

University of Medical Sciences

Full name of responsible person

Rahele Tavakoly

Position

phd candidate of nutrition Sciences

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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