

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Effect of fenugreek seed on anthropometric indicators, blood pressure, liver and kidney function, depression and anxiety in type 2 diabetic patients

Protocol summary

Summary

Study aim: determination of the Effect of fenugreek seeds on anthropometric indicators, blood pressure, liver and kidney function, depression and anxiety in type 2 diabetic patients. Study design: Randomized, controlled, no blinding, no placebo, single-center, parallel. Study population: Inclusion criteria: type 2 diabetes; 30-65 years old; at least 1 year and up to 10 year diabetic history; Body Mass Index < 35. Exclusion criteria: insulin therapy; menopause or hysterectomy for women; having any certain diseases or using any certain medications other than diabetic ones; allergy to Fabaceae family herbs; using dietary supplements and other medicinal plants for at least three months prior to the study; smoking or using drugs. Sample size: 48 persons. Random assignment method: Binary random block method. Intervention group: 15 grams of powdered fenugreek seeds in doses of 5 grams three times a day between meals, dissolved in water besides routine diabetic drugs. Control group: routine diabetic drugs. Duration of intervention: 8 weeks. Study outcomes: Waist circumference, Hip circumference, Lipid accumulation product index, Blood pressure, Alanine aminotransferase, Aspartate aminotransferase, Alkaline phosphatase, Blood urea nitrogen, Creatinine, estimated Glomerular filtration rate, Depression and Anxiety.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017072732294N3**

Registration date: **2017-08-21, 1396/05/30**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-08-21, 1396/05/30

Registrant information

Name

Rahele Tavakoly

Name of organization / entity

Isfahan University of Medical sciences

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2017-08-23, 1396/06/01

Expected recruitment end date

2017-11-22, 1396/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of fenugreek seed on anthropometric indicators, blood pressure, liver and kidney function, depression and anxiety in type 2 diabetic patients

Public title

Effect of Fenugreek on the Treatment of Diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: type 2 diabetes; 30-65 years old; at least 1 year and up to 10 year diabetic history; Body Mass Index<35 Exclusion criteria: insulin therapy; menopause or hysterectomy for women; having any certain diseases or using any certain medications other than diabetic ones; allergy to Fabaceae family herbs; using dietary supplements and other medicinal plants for at least three months prior to the study; smoking or using drugs

Age

From **30 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

Ethics committee of 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

Non-insulin-dependent diabetes mellitus

ICD-10 code

E11.9

ICD-10 code description

Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description

Hip circumference

Timepoint

baseline and 8 weeks after intervention

Method of measurement

measuring tape

2

Description

waist circumference

Timepoint

baseline and 8 weeks after intervention

Method of measurement

measuring tape

3

Description

blood pressure

Timepoint

baseline and 8 weeks after intervention

Method of measurement

sphygmomanometer

4

Description

Alanine Amino Transferase

Timepoint

baseline and 8 weeks after intervention

Method of measurement

blood sampling and commercial kits

5

Description

Aspartate aminotransferase

Timepoint

baseline and 8 weeks after intervention

Method of measurement

blood sampling and commercial kits

6

Description

Alkaline phosphatase

Timepoint

baseline and 8 weeks after intervention

Method of measurement

blood sampling and commercial kits

7

Description

Blood urea nitrogen

Timepoint

baseline and 8 weeks after intervention

Method of measurement

blood sampling and commercial kits

8

Description

Creatinine

Timepoint

baseline and 8 weeks after intervention

Method of measurement

blood sampling and commercial kits

9

Description

depression

Timepoint

baseline and 8 weeks after intervention

Method of measurement

"Hospital Anxiety and Depression Scale" questionnaire

10

Description

anxiety

Timepoint

baseline and 8 weeks after intervention

Method of measurement

"Hospital Anxiety and Depression Scale" questionnaire

Secondary outcomes

1

Description

Lipid accumulation product index

Timepoint

baseline and 8 weeks after intervention

Method of measurement

Formula calculation

2

Description

estimated glomerular filtration rate

Timepoint

baseline and 8 weeks after intervention

Method of measurement

Formula calculation

Intervention groups

1

Description

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

Category

Treatment - Other

2

Description

control: routine diabetic drugs for 8 weeks

Category

Treatment - Drugs

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 Yamini

Street address

Khorram Street, Jomhour Square

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Isfahan University of Medical Sciences

Full name of responsible person

Mehdi Nematbakhsh

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

Vice chancellor for research, 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

Isfahan University of Medical Sciences

Full name of responsible person

Rahele tavakoly

Position

PhD. candidate of nutrition sciences

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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