Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effect of fenugreek seed on anthropometric indicators, some blood factors, depression, and anxiety in type 2 diabetic patients

Protocol summary

Study aim
to examine the effects of fenugreek seeds on anthropometric indexes, some blood factors, depression, and anxiety in type 2 diabetic patients.

Design
parallel, randomized, controlled trial

Settings and conduct
setting: university clinics Fasting blood samples were drawn at baseline and end of the study to measure blood factors

Participants/Inclusion and exclusion criteria
type 2 diabetes; 30-65 years old; up to 10 year diabetic history; Body Mass Index<35; no insulin therapy; no menopause or hysterectomy (women); not having any certain diseases or not using any certain medications other than diabetic ones; not having allergy to Fabaceae family herbs; not using dietary supplements and other medicinal plants for at least three months prior to the study

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

Main outcome variables
anthropometric indexes, blood pressure, irisin, lipid profile, glycemic factors, kidney function. liver function, depression, anxiety

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190618043924N1**
Registration date: **2019-07-22, 1398/04/31**
Registration timing: **registered_while_recruiting**
Last update: **2019-07-22, 1398/04/31**
Update count: **0**

Registration date
2019-07-22, 1398/04/31

Registrant information

Name
Rahele Tavakoly

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 34 3132 5086

Email address
r.tavakoli@kmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-04-21, 1398/02/01

Expected recruitment end date
2019-07-23, 1398/05/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of fenugreek seed on anthropometric indicators, some blood factors, depression, and anxiety in type 2 diabetic patients

Public title
Effect of fenugreek seed on the treatment of diabetes

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

type 2 diabetes 30-65 years old up to 10 year diabetic history Body Mass Index<35

Exclusion criteria:

insulin therapy menopause or hysterectomy (women) having any certain diseases or using any certain medications other than diabetic ones having allergy to Fabaceae family herbs using dietary supplements and other medicinal plants for at least three months prior to the study

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: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

binary random block method Unit of randomization: individual Randomization strata: age, sex, body mass index Tools used in randomization: coin The allocation was concealed from the clinical recruitment staff until each patient had entered the trial and received a randomization code

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 Kerman university of medical sciences

Street address

Haft Bagh-E-Alavi Highway

City

Kerman

Province

Kerman

Postal code

7616913555

Approval date

2019-07-10, 1398/04/19

Ethics committee reference number

IR.KMU.REC.1398.188

Health conditions studied

1

Description of health condition studied

Non-insulin-dependent diabetes mellitus

ICD-10 code

E11

ICD-10 code description

Type 2 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
depression and anxiety
Timepoint
baseline and 8 weeks after intervention
Method of measurement
"Hospital Anxiety and Depression Scale" questionnaire

8

Description
irisin
Timepoint
baseline and 8 weeks after intervention
Method of measurement
blood sampling and commercial kits

9

Description
triglyceride
Timepoint
baseline and 8 weeks after intervention
Method of measurement
blood sampling and commercial kits

10

Description
Low-density lipoprotein
Timepoint
baseline and 8 weeks after intervention
Method of measurement
blood sampling and commercial kits

11

Description
high-density lipoprotein
Timepoint
baseline and 8 weeks after intervention
Method of measurement
blood sampling and commercial kits

12

Description
fasting plasma glucose
Timepoint
baseline and 8 weeks after intervention
Method of measurement
blood sampling and commercial kits

13

Description
2-h post prandial glucose
Timepoint
baseline and 8 weeks after intervention
Method of measurement
blood sampling and commercial kits

14

Description
insulin
Timepoint
baseline and 8 weeks after intervention
Method of measurement
blood sampling and commercial kits

15

Description
HbA1C
Timepoint
baseline and 8 weeks after intervention
Method of measurement
blood sampling and commercial kits

16

Description
Blood urea nitrogen
Timepoint
baseline and 8 weeks after intervention
Method of measurement
blood sampling and commercial kits

17

Description
Creatinine
Timepoint
baseline and 8 weeks after intervention
Method of measurement
blood sampling and commercial kits

Secondary outcomes

empty

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, besides routine diabetic drugs, for 8 weeks
Category
Treatment - Other

2

Description
Control group: routine diabetic drugs for 8 weeks
Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
University Clinics
Full name of responsible person
Morteza Hashemian
Street address
Haft Bagh-E-Alavi Highway
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Kerman
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7616913555
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Davood Kalantar
Street address
Haft Bagh-E-Alavi Highway
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Kerman
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7616913555
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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
Kerman University of Medical Sciences

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
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Rahele Tavakoly
Position
Assistant Professor
Latest degree
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Other areas of specialty/work
Nutrition
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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Only the data from the original outcomes can be shared
When the data will become available and for how long
the results will become available after publication
To whom data/document is available
some additional supporting information can be shared for anyone in academic institutions who applies
Under which criteria data/document could be used
using additional supporting information is just for receiving more details about the study and should not be used anywhere without the permission of the researchers
From where data/document is obtainable
for additional supporting information, you can email Dr. Rahele Tavakoly (tavakkoli.rahele@yahoo.com)
What processes are involved for a request to access data/document
1. Request letter 2. The reasons for the request and the type of uses of the additional supporting information 3. Applicant'sacademic profile and applicant's organization's name 4. An official contract with a signed and authentic signature from the applicant's organization that the use of the information is under the consent of the researchers.
Comments