Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

The Effect of Fenugreek Seed Extract Supplementation on Blood glucose,Lipid profile, Appetite, Energy Intake and Macronutrient, Oxidative stress in Patients with Type 2 Diabetes:Randomized Double-blind Controlled clinical Trial

Protocol summary

Study aim

Determining the effect of fenugreek seed extract supplement on serum levels of FBS, serum insulin and IR and serum levels of TG, HDL, LDL, TC and the amount of appetite and energy and macronutrient intake and the amount of oxidant and antioxidant balance (PAB) in individuals With T2DM

Design

This study is a randomized double-blind parallel clinical trial using the block Randomization method in which patients with type 2 diabetes will be divided into two subgroups of 23 complementary and placebo.

Settings and conduct

Patients with type 2 diabetes will be divided into two subgroups of 23 complementary and placebo using the Block Randomization method. Other than the researcher, they are coded as A and B. Patients will receive fenugreek seed extract in the form of three 335 mg tablets and the control group will receive three 335 mg placebo tablets daily for 8 weeks. Finally, the serum of the participants will be measured in terms of lipid parameters, fasting blood sugar, serum insulin and PAB.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1-Patients in the age range of 30-65 years 2-Having at least 6 months of diabetes history (according to criteria of American Diabetes Association) 3-BMI between 25 and 35 4-Taking blood sugar lowering drugs 5-Willingness to participate in the project Exclusion criteria: 1-Pregnancy or breastfeeding or its intention 2-Kidney, liver, gastrointestinal, thyroid, and rheumatic diseases

Intervention groups

Individuals in the supplement group will receive three 335 mg fenugreek seed extract tablets daily and the control group will receive three 335 mg placebo tablets daily.

Main outcome variables

Fasting blood sugar, lipid profile (HDL, LDL, TG, TC), PAB (oxidant and antioxidant balance)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210407050881N1**
Registration date: **2022-01-04, 1400/10/14**
Registration timing: **retrospective**

Last update: **2022-01-04, 1400/10/14**
Update count: **0**

Registration date

2022-01-04, 1400/10/14

Registrant information

Name

Fatemeh Chehregosha

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3762 4300

Email address

fatemehchehregosha4@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-06, 1400/05/15

Expected recruitment end date

2021-12-06, 1400/09/15

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Effect of Fenugreek Seed Extract Supplementation on Blood glucose,Lipid profile, Appetite, Energy Intake and Macronutrient, Oxidative stress in Patients with Type 2 Diabetes:Randomized Double-blind Controlled clinical Trial

Public title
Effect of fenugreek seed extract on oxidative stress in type 2 diabetic patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients in the age range of 30-65 years Having at least 6 months of diabetes history (according to criteria of American Diabetes Association) BMI between 25 and 35 Taking blood sugar lowering drugs No herbs at least 3 months before the study to be used routinely Willingness to participate in the project
Exclusion criteria:
Pregnancy or breastfeeding or its intention Kidney, liver, gastrointestinal, thyroid, and rheumatic diseases Allergy to plants of the Fabaceae family
Age
From **30 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **46**
Randomization (investigator's opinion)
Randomized
Randomization description
Subjects using RAS software (Random allocation software) and randomly, using the method of random blocking (block randomization) in terms of classification on body mass index (25-30 or 35-30 kg / m2) And gender (female or male) and inclusion in the study in the form of 4 groups and blocks with size of 6 , are divided into 2 groups of 23 people.
Blinding (investigator's opinion)
Double blinded
Blinding description
For double-blind research, at the beginning of the study, a set of cans containing the corresponding capsule, which are similar in appearance (color, odor, size, shape), are coded A and B by someone other than the researcher until the researcher is informed. And patients of the type of capsules received by each group.The drug and placebo were similar in characteristics and appearance (color, odor, size)
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences
Street address
Factulty of Nutrition, Tabriz University of Medical Sciences, Golgasht St, Attar Neyshabouri St., Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5166616471
Approval date
2021-08-02, 1400/05/11
Ethics committee reference number
IR.TBZMED.REC.1400.242

Health conditions studied

1

Description of health condition studied
Type 2 diabetes mellitus
ICD-10 code
E11
ICD-10 code description
Type 2 diabetes mellitus

Primary outcomes

1

Description
Fasting blood suger
Timepoint
Before intervention and 2 months after intervention
Method of measurement
Measurement of blood levels using electrochemical methods

2

Description
serum insulin
Timepoint

Before intervention and 2 months after intervention

Method of measurement

Measurement of serum level by ELISA kit

3

Description

insulin resistance

Timepoint

Before intervention and 2 months after intervention

Method of measurement

Formula calculation

4

Description

Triglyceride

Timepoint

Before intervention and 2 months after intervention

Method of measurement

Measurement of serum level using spectrophotometric method

5

Description

LDL

Timepoint

Before intervention and 2 months after intervention

Method of measurement

Friedwald Computational Method

6

Description

HDL

Timepoint

Before intervention and 2 months after intervention

Method of measurement

Measurement of serum level using spectrophotometric method

7

Description

total cholestrol

Timepoint

Before intervention and 2 months after intervention

Method of measurement

Measurement of serum level using spectrophotometric method

8

Description

PAB

Timepoint

Before intervention and 2 months after intervention

Method of measurement

Measurement of serum level by ELISA kit

9

Description

Appetite

Timepoint

Before intervention and 2 months after intervention

Method of measurement

questionnaire

10

Description

Calorie intake

Timepoint

Before intervention and 2 months after intervention

Method of measurement

questionnaire(Finally, energy calculation using n4 software)

11

Description

macronutrients intake

Timepoint

Before intervention and 2 months after intervention

Method of measurement

n4 software

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Dry extract of fenugreek seeds of Barij Essential Oil Company called "Glucorx B" (containing 46.4 micrograms of luteolin per tablet) will be consumed in the form of three 335 mg tablets. The study population in this study is people with type 2 diabetes who need to receive diet and nutritional advice due to ethical considerations. According to the available reference (Krause), the prescribed regimen should be appropriate to the clinical condition of each patient; Therefore, the amount of reduction in calories per person will not be a fixed amount. To calculate calories, BMR (using the Myfeline formula) will be multiplied by physical activity and TEF. People in this group are on a diabetic and calorie-restricted diet for 8 weeks. The relevant food menu will be taught to patients along with nutritional recommendations.

Category

Treatment - Drugs

2

Description

Control group: will consume three 335 mg placebo tablets made of microcrystalline cellulose prepared by Barij Essential Oil Company. The study population in this study is people with type 2 diabetes who need to receive

diet and nutritional advice due to ethical considerations. According to the available reference (Krause), the prescribed regimen should be appropriate to the clinical condition of each patient; Therefore, the amount of reduction in calories per person will not be a fixed amount. To calculate calories, BMR (using the Myfeline formula) will be multiplied by physical activity and TEF. People in this group are on a diabetic and calorie-restricted diet for 8 weeks. The relevant food menu will be taught to patients along with nutritional recommendations.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Nutrition Research Laboratory, Faculty of Nutrition, University of Medical Sciences

Full name of responsible person
Zhila Sadeghi

Street address
Faculty of Nutrition - Tabriz University of Medical Sciences - Golgasht St. - Attar Neyshabouri St. - Tabriz - Iran

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Tabriz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Ali Tarighat Esfanjani

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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
Tabriz 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
Tabriz University of Medical Sciences

Full name of responsible person
Fatemeh Chehregosha

Position
Master of sience in clinical nutrition

Latest degree
Bachelor

Other areas of specialty/work
Nutrition

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Faculty of Nutrition - Tabriz University of Medical Sciences - Golgasht St. - Attar Neyshabouri St. - Tabriz - Iran

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Fatemeh Chehregosha

Position
Master of sience in clinical nutrition

Latest degree
Bachelor

Other areas of specialty/work
Nutrition

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Person responsible for updating data

Contact

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Position
Master of sience in clinical nutrition

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Nutrition

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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