

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 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 / m<sup>2</sup>) 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**

Faculty 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 sugar

**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 cholesterol

**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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**Email**

nutritionfaculty@tbzmed.ac.ir

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Ali Tarighat Esfanjani

**Street address**

Faculty of Nutrition - Tabriz University of Medical  
Sciences - Golgasht St. - Attar Neyshabouri St. -  
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info@tbzmed.ac.ir

**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 science in clinical nutrition

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nutrition

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Fatemeh Chehregosha

**Position**

Master of science in clinical nutrition

**Latest degree**

Bachelor

**Other areas of specialty/work**

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