

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 2026

### The Effect of Fenugreek Seed Extract Supplementation on Body Composition, Blood Pressure, IL-1 $\beta$ , Adiponectin, and Depression in Patients with Type 2 Diabetes: Randomized Double-Blind Controlled Clinical Trial

#### Protocol summary

##### Study aim

Determining the effect of dry fenugreek seed extract on body composition, blood pressure, IL-1 $\beta$ , adiponectin, and depression in people with type 2 diabetes

##### Design

This study is a controlled parallel, and double-blind, phase 3 clinical trial, which is randomized using the Block Randomisation method.

##### Settings and conduct

Type 2 diabetics will be divided into the supplementation and placebo groups, each with 23 people. For being double-blind research, at the beginning of the study, the boxes of tablets will be coded in A and B by someone other than the researcher. Assessments including anthropometric indices, blood pressure, and depression questionnaire will be measured and completed at the beginning and end of the study for all individuals in the Nutrition Faculty of Tabriz University of Medical Sciences. Blood samples will also be collected to measure IL-1 $\beta$  and adiponectin. The supplement group will receive three 335 mg fenugreek seed extract tablets daily and the control group will receive three 335 mg placebo tablets.

##### Participants/Inclusion and 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  
Non inclusion Criteria: -Pregnancy or breastfeeding or its intention -Kidney, liver, gastrointestinal, thyroid, and rheumatic diseases -Allergy to plants of the Fabaceae family

##### Intervention groups

The supplement group will receive three 335 mg

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

##### Main outcome variables

Body composition; blood pressure; IL-1 $\beta$ ; Adiponectin; Depression

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210407050880N1**

Registration date: **2021-12-25, 1400/10/04**

Registration timing: **retrospective**

Last update: **2021-12-25, 1400/10/04**

Update count: **0**

##### Registration date

2021-12-25, 1400/10/04

##### Registrant information

##### Name

Laleh Fakhr

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 3330 5336

##### Email address

lalehfakhrnut@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 Body Composition, Blood Pressure, IL-1 $\beta$ , Adiponectin, and Depression in Patients with Type 2 Diabetes: Randomized Double-Blind Controlled Clinical Trial

**Public title**

Effect of Fenugreek Seed Extract on inflammation in Patients with Type 2 Diabetes

**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 are randomly divided into two groups of 23 people, by application of RAS software (Random allocation software) and using block randomization method according to the classification on body mass index (30-25 or 35-30 kg/m<sup>2</sup>) and gender (male or female), and in the form of 4 groups and blocks of 2 people.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

For being double-blind research, at the beginning of the study, the boxes of capsules will be coded in A and B by someone other than the researcher, so that the researcher and patients won't be informed about the type of capsules received by each group.

**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 - Iran

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166616471

**Approval date**

2021-08-02, 1400/05/11

**Ethics committee reference number**

IR.TBZMED.REC.1400.399

**Health conditions studied****1****Description of health condition studied**

Type 2 Diabetes

**ICD-10 code**

E11

**ICD-10 code description**

Type 2 diabetes mellitus

**Primary outcomes****1****Description**

Inflammatory marker IL-1 $\beta$

**Timepoint**

Before intervention and 2 months after intervention

**Method of measurement**

Measurement of serum level by ELISA kit

**2****Description**

Adiponectin

**Timepoint**

Before intervention and 2 months after intervention

**Method of measurement**

Measurement of serum level by ELISA kit

### 3

#### **Description**

Body Composition

#### **Timepoint**

Before intervention and 2 months after intervention

#### **Method of measurement**

By Tanita Body Analyzer

### 4

#### **Description**

Blood pressure

#### **Timepoint**

Before intervention and 2 months after intervention

#### **Method of measurement**

Mercury barometer

### 5

#### **Description**

Depression

#### **Timepoint**

Before intervention and 2 months after intervention

#### **Method of measurement**

PHQ-9 questionnaire

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group: Dry extract of fenugreek seeds of Barij Essence Company entitled "Glucorx B" (containing 46.4 micrograms of luteolin per tablet), in the form of three 335 mg tablets and diet for eight weeks. This study's population 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 each patient's clinical condition; Therefore, reducing calories per person will not be a fixed amount. BMR (using the Mifflin formula) will be multiplied by physical activity and TEF to calculate calories. People in this group will be on a diabetic and calorie-restricted diet. The relevant menu will be taught to patients, along with nutritional recommendations.

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Control group: This group will take three 335 mg placebo tablets, made of microcrystalline cellulose, prepared by Barij Essence Company and diet for eight weeks. This study's population 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 each patient's clinical condition; Therefore, reducing calories per person will not be a fixed amount. BMR (using the Mifflin formula) will be multiplied by physical activity and TEF to calculate calories. People in this group will be on a diabetic and calorie-restricted diet. The relevant 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

##### **City**

Tabriz

##### **Province**

East Azarbaijan

##### **Postal code**

5166616471

##### **Phone**

+98 41 3335 5921

##### **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. - Tabriz - Iran

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Tabriz

##### **Province**

East Azarbaijan

##### **Postal code**

5166616471

##### **Phone**

+98 41 3335 5921

##### **Email**

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**

Laleh Fakhr

**Position**

Master of Science in Clinical Nutrition

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nutrition

**Street address**

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

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166616471

**Phone**

+98 41 3335 5921

**Email**

lalehfakhrnut@gmail.com

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Laleh Fakhr

**Position**

Master of Science in Clinical Nutrition

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nutrition

**Street address**

Faculty of Nutrition - Tabriz University of Medical

Sciences - Golgasht St. - Attar Neyshabouri St. - Tabriz - Iran

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166616471

**Phone**

+98 41 3335 5921

**Email**

lalehfakhrnut@gmail.com

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Laleh Fakhr

**Position**

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**Latest degree**

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**Email**

lalehfakhrnut@gmail.com

## 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