Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jul 2026

The Effect of Fenugreek Seed Extract Supplementation on Body Composition, Blood Pressure, IL-1β, 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-1β, 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-1β 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-1β; 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)
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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-1β, 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/m2) 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-1β
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
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Faculty of Nutrition - Tabriz University of Medical Sciences - Golgasht St. - Attar Neyshabouri St. - Tabriz - Iran
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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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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

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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
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Master of Science in Clinical Nutrition

Latest degree
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Person responsible for updating data

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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