Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the combined efficacy of berberine and fenugreek in controlling blood glucose and lipid profile and inflammatory factors in type 2 diabetic patients

Protocol summary

Study aim
The effect of supplementation with berberine and fenugreek on inflammatory factors, lipid profile and glucose profile in patients with type 2 diabetes

Design
The clinical trial has control and intervention groups in parallel, double blind and randomized.

Settings and conduct
In this study, subjects were divided into two groups of 25 patients receiving berberine and fenugreek and placebo supplementation. Fenugreek seed) and patients in the placebo group (wheat flour) also take 3 capsules that are similar in appearance to supplements half an hour before the main meal for 12 weeks. Cans containing capsules and how to use them were coded by a non-researcher as an allocation concealment for lack of information. Observe the type of capsules received.

Participants/Inclusion and exclusion criteria
Inclusion criteria (above 25BMI, having at least 1 year history of diabetes, no pregnancy and lactation, no chronic illnesses, etc.)Exclusion criteria (Pregnant and lactating women, history of drug or alcohol use in the past 6 months, use of steroidal anti-inflammatory drugs and fiber supplements, weight loss diet at least 6 months before intervention, etc.)

Intervention groups
Patients were divided into two groups of 25 patients receiving berberine and fenugreek and placebo supplementation. In this study, patients were given the respective supplements for 12 weeks according to their placebo group. Together with berberine and fenugreek 3 capsules daily 500 mg (300 mg berberine +200 mg fenugreek seed powder) and patients in the placebo group (wheat flour) 3 capsules that are similar in appearance to supplements half an hour before the main meal.

Main outcome variables
Inflammatory factors; lipid profile and blood glucose

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20191229045937N1**
Registration date: **2020-02-02, 1398/11/13**
Registration timing: **registered_while_recruiting**

Last update: **2020-02-02, 1398/11/13**
Update count: **0**

Registration date
2020-02-02, 1398/11/13

Registrant information

Name
Shima Nematollahi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-12-29, 1398/10/08

Expected recruitment end date
2021-03-18, 1399/12/28

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the combined efficacy of berberine and fenugreek in controlling blood glucose and lipid profile and inflammatory factors in type 2 diabetic patients

Public title
The Effect of Combined Supplementation of Berberine and Fenugreek Seed Powder on Inflammatory Factors and Lipid and Glucose Profile in Patients with Type 2 Diabetes

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Having over 25BMI, at least 1 year of diabetes, 25-65 year olds with type 2 diabetes, taking blood sugar lowering diabetes medications, no pregnancy and lactation, no chronic diseases (liver, kidney, heart, thyroid, Rheumatic, Pulmonary, Metabolic, Digestive, Malignancies, Allergies), No insulin requirement, No use of dietary supplements, vitamins and minerals at least 3 months before study, No hormone therapy, No smoking, No use of other medicinal products Routine face at least 3 months before study, written informed consent from patients at least 1 year of diabetes 25-65 year olds with type 2 diabetes taking blood sugar lowering diabetes medications no pregnancy and lactation no chronic diseases (liver, kidney, heart, thyroid, Rheumatic, Pulmonary, Metabolic, Digestive, Malignancies, Allergies) No insulin requirement No use of dietary supplements, vitamins and minerals at least 3 months before study No hormone therapy No smoking No use of other medicinal products Routine face at least 3 months before study written informed consent from patients

Exclusion criteria:
Not willing to continue cooperation Specific diseases (liver, kidney, heart, thyroid, rheumatic, pulmonary, metabolic, gastrointestinal, malignant, allergic) during study pregnancy initiation and lactation Start insulin treatment Start taking supplements, vitamins and minerals Changes in the dosage of oral hypoglycemic agents Changes in the amount of physical activity during the study Start taking other medicinal products routinely Pregnant and lactating women Past 6 months drug or alcohol use history Taking steroidal anti-inflammatory drugs and fiber supplements Weight loss diet at least 6 months before the intervention Use of dietary supplements and other herbal remedies at least 3 months before intervention

Age
From **25 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization Method: Block Randomization Tool: Statistical Software

Blinding (investigator's opinion)
Double blinded

Blinding description
1. Split people into 2 groups based on age group randomly blocked using 3-way blocks (split: 25-35 / 35-45 / 45-65). 2. Double blinding blind before coding the set of cans containing capsules and how to use them, coded by a non-researcher as a allocation concealment to ensure that the researcher does not know the type of capsules received.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address
Golestan Medical Sciences Dormitory, Golestan Boulevard, Ahvaz, Khouzestan, Iran

City
Ahvaz

Province
Khouzestan

Postal code
6135815751

Approval date
2019-12-28, 1398/10/07

Ethics committee reference number
IR.AJUMS.REC.1398.735

Health conditions studied

1

Description of health condition studied
Type 2 diabetes

ICD-10 code
E08

ICD-10 code description
Diabetes mellitus due to underlying condition

Primary outcomes

1

Description
Inflammatory factors and lipid and sugar profiles
Timepoint
Evaluation of inflammatory factors and lipid profile and glucose profile at baseline and 12 weeks after starting supplementation with berberine and fenugreek
Method of measurement
Blood serum separation

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: We selected 25 patients with type 2 diabetes between the ages of 25-65 years based on inclusion and exclusion criteria. Each person consumes 3 capsules of 500 mg daily (300 mg of berberine + 200 mg of fenugreek seed powder) before three main meals and this intervention lasts 12 weeks
Category
Treatment - Drugs

2

Description
Control group: We selected 25 patients with type 2 diabetes between the ages of 25-65 years based on inclusion and exclusion criteria. Each person consumes 3 capsules of 500 mg daily (500 mg of wheat flour) before 3 servings and this intervention lasts 12 weeks.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Diabetes Clinic
Full name of responsible person
shima nematollahi
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Golestan Medical Sciences Dormitory, Golestan Boulevard, Ahvaz, Khouzestan, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Ahvaz 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
Ahvaz University of Medical Sciences
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Position
Senior students
Latest degree
Bachelor
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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
Survey the effect of co-supplementation of berberine and fenugreek seed powder on inflammatory factors glycemic and lipid profile in patients with type 2 diabetes mellitus
When the data will become available and for how long
One year and two months
To whom data/document is available
researchist
Under which criteria data/document could be used
Prevention and treatment of people with type 2 diabetes
From where data/document is obtainable
laboratory
What processes are involved for a request to access data/document
Double-blind random sampling
Comments