

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

Inflammatory factors; lipid profile and blood glucose

##### 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

#### 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 5800 6143

##### Email address

shimanematollahi7@gmail.com

##### 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, Khuzestan, Iran

**City**

Ahvaz

**Province**

Khuzestan

**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

##### Street address

Golestan Medical Sciences Dormitory, Golestan Boulevard, Ahvaz, Khuzestan, Iran

##### City

Ahvaz

##### Province

Khuzestan

##### Postal code

6135815751

##### Phone

+98 71 5800 6143

#### Email

Shimanematollahi7@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Ahvaz University of Medical Sciences

##### Full name of responsible person

Dr. badavi

##### Street address

Golestan Medical Sciences Dormitory, Golestan Boulevard, Ahvaz, Khuzestan, Iran

##### City

Ahvaz

##### Province

Khuzestan

##### Postal code

6135815751

##### Phone

+98 71 5800 6143

##### Email

Shimanematollahi7@gmail.com

#### 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

##### Full name of responsible person

Shima Nematollahi

##### Position

Senior students

##### Latest degree

Bachelor

##### Other areas of specialty/work

Nutrition

##### Street address

Golestan Medical Sciences Dormitory, Golestan Boulevard, Ahvaz, Khuzestan, Iran

##### City

Ahvaz

**Province**

Khouzestan

**Postal code**

6135815751

**Phone**

+98 61 3321 4578

**Email**

Shimanematollahi7@gmail.com

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

Ahvaz University of Medical Sciences

**Full name of responsible person**

Fatemeh Borazjani

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

**Street address**

Golestan Boulevard Golestan Medical Sciences

Dormitory

**City**

Ahvaz

**Province**

Khouzestan

**Postal code**

6135815751

**Phone**

+98 61 3321 4578

**Email**

fa.borazjani@gmail.com

**Person responsible for updating data****Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Shima Nematollahi

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nutrition

**Street address**

Shams Ave..Artesh Blvr.,Sadra faz 2 Town

**City**

Shiraz

**Province**

Fars

**Postal code**

6135815751

**Phone**

+98 71 5800 6143

**Fax****Email**

shimanematollahi7@gmail.com

**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**