

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

15 Oct 2026

### Effect of Psyllium and Flaxseed on glucose, lipids, and constipation in patients with type 2 diabetes and chronic constipation

#### Protocol summary

##### Study aim

To compare effects of psyllium and flaxseed supplement versus those who received a placebo on glycemic and lipids control and constipation in patients with type 2 diabetes (T2D) and chronic constipation.

##### Design

single-blinded, randomized controlled trial. 90 patients with T2D and chronic constipation will receive either 10 grams of psyllium mixed in biscuit twice per day or 10 grams of flaxseed mixed in biscuit twice per day or placebo biscuit for 12 weeks. Fasting plasma glucose, glycosylated hemoglobin (HbA1c), and lipid profile, as well as the constipation score, will be determined at the beginning and end of 4, 8, and 12-week period. constipation will be a score on the ROME III rating scale .

##### Settings and conduct

This is a single-blinded, randomized placebo-control trial of 90 consecutive patients with T2D and symptoms of chronic constipation attending outpatient clinics in Isfahan Endocrine and Metabolism Research Center .

##### Participants/Inclusion and exclusion criteria

Patients will be included if they had a bowel movement frequency of < 3/week during the past three months; age ≥30 years and diabetes duration > 1 year. Patients will be excluded from the study if they had type 1 diabetes, weight loss, lipid-lowering drug treatment, fiber supplementation, anorectal problems, abdominal pain, and history of opioid use in the last 48 h, any other factors which would interfere with constipation assessment and management, or pre-existing severe cardiac, endocrinological, hematological, hepatic, renal, metabolic, neurological or psychiatric disorders. Pregnant or nursing women will be excluded. Non-compliant patients during baseline or treatment phases as evaluated by taking <75% of either of the test articles during a one-week period throughout the course of the study will be excluded from the evaluable patient data analysis.

##### Intervention groups

Participants in the control group will be received psyllium and sugar-free orange-flavored maltodextrin cookies for 12 weeks as placebo. The psyllium group will be received 10 g psyllium premixed in a sugar-free orange-flavored maltodextrin cookies twice per day for 12 weeks. The flaxseed group will be received 10 g flaxseed premixed in a sugar-free orange-flavored maltodextrin cookies twice per day for 12 weeks.

##### Main outcome variables

Primary outcome measures will be included analysis of numerical values of constipation intensity. Secondary outcome measures will be included analysis of the body weight, glycemic and lipid control.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20110416006202N2**

Registration date: **2017-12-29, 1396/10/08**

Registration timing: **registered\_while\_recruiting**

Last update: **2017-12-29, 1396/10/08**

Update count: **0**

##### Registration date

2017-12-29, 1396/10/08

##### Registrant information

##### Name

Mohsen Janghorbani

##### Name of organization / entity

Isfahan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

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##### Email address

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##### Recruitment status

**Recruitment complete**

**Funding source**  
Isfahan Endocrine and Metabolism Research Center

**Expected recruitment start date**  
2017-09-23, 1396/07/01

**Expected recruitment end date**  
2018-02-20, 1396/12/01

**Actual recruitment start date**  
empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
Effect of Psyllium and Flaxseed on glucose, lipids, and constipation in patients with type 2 diabetes and chronic constipation

**Public title**  
Effect of Psyllium and Flaxseed on glucose, lipids, and constipation

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Patients were included if they had type 2 diabetes. A bowel movement frequency of < 3/week during the past three months.  
**Exclusion criteria:**  
Patients were excluded from the study if they had weight loss, rectal bleeding abdominal pain history of opioid use in the last 48 h pre-existing severe cardiac endocrinological hematological hepatic renal metabolic neurological or psychiatric disorders Pregnant or nursing women will be excluded Non-compliant patients during baseline or treatment phases as evaluated by taking <75% of either of the test articles during a one-week period throughout the course of the study will be excluded from the evaluable patient data analysis.

**Age**  
From **30 years** old to **75 years** old

**Gender**  
Both

**Phase**  
2-3

**Groups that have been masked**

- Participant
- Data analyser

**Sample size**  
Target sample size: **90**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Patients were randomized according to a preexisting list produced by a computer program that differed from a random number generator only in that it assigned equal numbers of patients to each treatment group, and the group assignments were concealed in an opaque sealed envelope.

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
The trial is single-blinded in that patients will be blind to the treatment. Masking of the two treatments was preserved by creating cookies that looked, tasted, and textured identically. The differences in taste were minimal because the prominent flavor was that of the orange-flavor in which cookies was mixed. Because each participant received only one kind of cookie, the participant had no way to compare their cookie with the other.

**Placebo**  
Used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Isfahan University of Medical Sciences ethic committee

##### Street address

Hezarjerib

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8184935331

#### Approval date

2015-04-21, 1394/02/01

#### Ethics committee reference number

IR.MUI.REC.1396.3.464

## Health conditions studied

### 1

#### Description of health condition studied

Constipation

#### ICD-10 code

K59.0

#### ICD-10 code description

Constipation

### 2

#### Description of health condition studied

Cholesterol and lipid metabolism

#### ICD-10 code

E78.7

#### ICD-10 code description

Disorders of bile acid and cholesterol metabolism

### 3

#### **Description of health condition studied**

Elevated blood glucose

#### **ICD-10 code**

R73

#### **ICD-10 code description**

Elevated blood glucose level

### 4

#### **Description of health condition studied**

BMI

#### **ICD-10 code**

Z68

#### **ICD-10 code description**

Body mass index [BMI]

## **Primary outcomes**

### 1

#### **Description**

constipation intensity

#### **Timepoint**

Beginning, 4, 8, 12 week after intervention

#### **Method of measurement**

ROME III

### 2

#### **Description**

body weight.

#### **Timepoint**

Beginning, 4, 8, 12 week after intervention

#### **Method of measurement**

Body mass index and body weight.

### 3

#### **Description**

lipids .

#### **Timepoint**

Beginning, 4, 8, 12 week after intervention

#### **Method of measurement**

Routine measurement of total cholesterol, triglyceride, low-density lipoprotein cholesterol, high-density lipoprotein cholesterol,

### 4

#### **Description**

fasting plasma glucose .

#### **Timepoint**

Beginning, 4, 8, 12 week after intervention

#### **Method of measurement**

Oxidase method.

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention 2: 10 grams of psyllium mixed in cookies twice per day for 12 weeks. Kamvar Co., Isfahan, Iran

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Intervention 1:10 grams of faxseed mixed in cookies twice per day for 12 weeks. Kamvar Co., Isfahan, Iran

#### **Category**

Treatment - Drugs

### 3

#### **Description**

Control group: Participants in the control group will be received psyllium, faxseed and sugar-free orange-flavored maltodextrin cookies for 12 weeks as placebo. Kamvar Co., Isfahan, Iran

#### **Category**

Placebo

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Isfahan Endocrine and Metabolism Research Center

##### **Full name of responsible person**

Ashraf Aminorroaya

##### **Street address**

Sedigheh Tahereh Research omplex, Khoram Ave

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## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Esfahan University of Medical Sciences

##### **Full name of responsible person**

Dr. Movahedian

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 research@mui.ac.ir  
**Web page address**  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
 Yes  
**Title of funding source**  
 Esfahan 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**  
 Isfahan Endocrin and Metabolism Research Center  
**Full name of responsible person**  
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## Person responsible for scientific inquiries

**Contact**  
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## Person responsible for updating data

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**Full name of responsible person**  
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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**  
Yes - There is 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**  
Yes - There is a plan to make this available  
**Title and more details about the data/document**  
Publish paper

**When the data will become available and for how long**  
starting in March 2018  
**To whom data/document is available**  
both people in academic and business  
**Under which criteria data/document could be used**  
undecided yet  
**From where data/document is obtainable**  
From M. Janghorbani janghorbani@yahoo.com  
**What processes are involved for a request to access data/document**  
Contact with the corresponding person.  
**Comments**