

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jun 2026

### The assessment of effects of flaxseed on insulin resistance serum, components of metabolic syndrome (lipids profiles, waist circumference and fasting glucose) and serum levels of cytokines secreted from adipose tissue in patients with ulcerative colitis

#### Protocol summary

##### Study aim

Determining and comparing the effect of flax consumption on the parameters of metabolic syndrome  
Determining and comparing the effects of flax consumption on fasting serum insulin concentration and insulin resistance index (HOMA-IR)  
Determining and comparing the effects of flax consumption on serum concentrations of adipokines - Determining and comparing the effects of flax consumption on serum concentrations of cytokines

##### Design

A clinical trial is a controlled clinical trial and open-label.  
Target population: 64 patients with ulcerative colitis who are divided into 32 groups

##### Settings and conduct

In this study, patients with ulcerative colitis will refer to the gastrointestinal clinic. Among them, the subjects will be followed for 3 months. They receive themselves, they are divided. Blood samples, nutritional and demographic assessments are taken from patients at the beginning and end of the study.

##### Participants/Inclusion and exclusion criteria

inclusion criteria: -Ulcerative colitis that is histopathologically confirmed. -The duration of ulcerative colitis should be at least 3 months. - Patients should be in the active stage of the disease. exclusion criteria: - Suffering from other intestinal diseases and disorders, autoimmune diseases, cancer, inflammatory - Diabetes or hyperlipidemia or drugs that affect the lipid profile - Consumption of anti-TNF alpha - immunomodulatory modulators

##### Intervention groups

Patients with mild to moderate disease are divided into two groups receiving 30 grams of ground flaxseed powder daily and the group of patients who do not receive any supplements and receive only the

recommendations and routine medical medications.

##### Main outcome variables

Metabolic syndrome parameters, insulin resistance index, adipokine

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20201229049878N1**

Registration date: **2022-06-26, 1401/04/05**

Registration timing: **retrospective**

Last update: **2022-06-26, 1401/04/05**

Update count: **0**

##### Registration date

2022-06-26, 1401/04/05

##### Registrant information

##### Name

Nava Morshedzadeh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 34 3132 5000

##### Email address

n.morshedzadeh@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-01-20, 1399/11/01

##### Expected recruitment end date

2022-02-20, 1400/12/01  
**Actual recruitment start date**  
empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty

**Scientific title**  
The assessment of effects of flaxseed on insulin resistance serum, components of metabolic syndrome (lipids profiles, waist circumference and fasting glucose) and serum levels of cytokines secreted from adipose tissue in patients with ulcerative colitis

**Public title**  
Flaxseed on insulin resistance in ulcerative colitis

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Age 18 to 55 years Body Mass Index (BMI) 18.5 and above Histopathologically confirmed ulcerative colitis The duration of ulcerative colitis should be at least 3 months. No change in the type and dose of medication used during the last 3 months Patients are in the active stage (mild to moderate) of the disease. Willingness to cooperate in this project

**Exclusion criteria:**

Other intestinal diseases and disorders, autoimmune diseases, cancer, inflammatory and infectious diseases Diabetes or hyperlipidemia (taking drugs that stimulate insulin secretion (such as glibenclamide) or drugs that affect lipid profile (such as statins)) History of gastrointestinal surgery Having other gastrointestinal diseases or gastrointestinal surgery during the study Pregnancy and lactation Use of anti-TNF alpha or immunomodulatory drugs (methotrexate and prednisolone) at or during the study

**Age**  
From **18 years** old to **55 years** old

**Gender**  
Both

**Phase**  
0

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **64**

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

**Randomization description**  
Patients were randomly assigned to the groups by randomly tapping the cards into 2 groups: 1) daily recipient of 30 grams of flaxseed in fully ground powder 2) group of patients who do not receive any supplements and only use routine medical advice and medications They will receive themselves, they will be divided. In this method, three different categories of cards were selected, each of which had the characteristics of one of the study groups by the two-score method. Participants randomly withdrew one card from each category. And

were included in that study group  
**Blinding (investigator's opinion)**  
Not blinded  
**Blinding description**  
**Placebo**  
Not used  
**Assignment**  
Parallel  
**Other design features**

**Secondary Ids**  
empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Ethics Committee of Shahid Beheshti University of Medical Sciences

**Street address**

Arabi Ave, Daneshjoo Blvd, Velenjak

**City**

Tehran

**Province**

Tehran

**Postal code**

19839-63113

**Approval date**

2018-11-27, 1397/09/06

**Ethics committee reference number**

IR.SBMU.ENDOCRINE.REC.1397.115

**Health conditions studied**

1

**Description of health condition studied**

Men and women aged 55-18 years with ulcerative colitis (mild to moderate)

**ICD-10 code**

K51

**ICD-10 code description**

Ulcerative colitis

**Primary outcomes**

1

**Description**

Metabolic syndrome parameters (fasting glucose, triglycerides, cholesterol, waist circumference and blood pressure)

**Timepoint**

3 month

**Method of measurement**

Measurement of blood pressure using mercury sphygmomanometer - Glucose by enzymatic method and using glucose oxidase, total cholesterol by enzymatic method and Cholesterol estrogen and cholesterol

oxidase are measured enzymatically using glycerol phosphate oxidase.

## 2

### **Description**

Insulin Resistance Index

### **Timepoint**

3month

### **Method of measurement**

The Homeostasis Model Assessment of IR (HOMA-IR) has proved to be a robust tool for the surrogate assessment of IR.  $MA-IR = (\text{glucose in mmol/L} \times \text{insulin in mIU/mL}) / 22.5$

## 3

### **Description**

Serum concentrations of adipokine (resistin and visfatin

### **Timepoint**

3month

### **Method of measurement**

using ELISA method and special kit instructions.

## 4

### **Description**

Serum concentrations of cytokines (interleukin-1 beta and tumor necrosis factor alpha)

### **Timepoint**

3month

### **Method of measurement**

using ELISA method and special kit instructions.

## 5

### **Description**

Severity of recurrent colitis

### **Timepoint**

3month

### **Method of measurement**

Severity of recurrent colitis based on Mayo score questionnaire

## 6

### **Description**

Evaluation of food intake

### **Timepoint**

3month

### **Method of measurement**

Evaluation of food intake using food frequency questionnaire 168 items

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group1: Receiver of 30 grams of flaxseed per day in the form of fully ground powder-whole flaxseed was ground and sealed in 250 g packages with a 30 g portion and given to patients. Mix and eat after breakfast

#### **Category**

Lifestyle

### 2

#### **Description**

Intervention group2: Intervention group 2: 7 grams of flaxseed oil per day, which is placed in a special container for patients

#### **Category**

Lifestyle

## **Recruitment centers**

### 1

#### **Recruitment center**

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

Taleghani Hospital, Tehran

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

parvin mirmiran

##### **Street address**

Velenjak St. , Shahid Chamran Highway

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##### **Province**

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##### **Phone**

+98 21 2303 1100

##### **Email**

n.morshedzadeh@yahoo.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

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

Shahid Beheshti University of Medical Sciences

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

parvin mirmiran

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#### **Grant name**

Shahid Beheshti University of Medical Sciences

**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Shahid Beheshti 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**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Nava Morshedzadeh  
**Position**  
Ph. D  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Nutrition  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**  
No - There is not a plan to make this available  
**Justification/reason for indecision/not sharing IPD**  
"There is no further information"  
**Study Protocol**  
No - There is not a plan to make this available  
**Statistical Analysis Plan**  
No - There is not 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**  
Not applicable  
**Analytic Code**  
Not applicable  
**Data Dictionary**  
Not applicable