

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 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

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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

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Velenjak St. , Shahid Chamran Highway

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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
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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