

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Effects of flaxseed consumption and flax oil supplement on serum levels of inflammatory markers, adipokines, and components of metabolic syndrome and severity of disease in patients with ulcerative colitis

Protocol summary

Study aim

-Determine and compare the effects of flaxseed supplementation of linseed oil on serum levels of inflammatory markers TNF- α , IFN-g, IL-1 β , IL-6, CRP, IL-10, TGF- β , adipokine (resistin and visfatin) and expression of TLR 4 (Toll-like receptor4) in white blood cells in three groups

Design

This study is an interventional study that is conducted by randomized controlled clinical trial and open-label method.

Settings and conduct

Patients with confirms UC by a gastroenterologist according to established clinical guidelines and criteria based on endoscopic, radiological and histopathological examination will be recruited into the study. The patients will be randomly divided into two Supplementation groups and one control group. Patients will be randomly assigned to take 7 gram flaxseed oil (group A) , 30 gram ground flaxseed (group B) once daily for 12 weeks and group C without receiving any supplements.

Participants/Inclusion and exclusion criteria

Mild to moderate ulcerative colitis; Other diseases and intestinal disorders, autoimmune diseases, cancer, inflammatory and infectious diseases

Intervention groups

Men and women aged 55-18 years with ulcerative colitis (mild to moderate) Patients were randomly divided into 3 groups: 1) daily intake of 30 grams of flaxseed ; 2) daily supplement 10 grams of flaxseed oil; 3) a group of patients who do not receive any supplement and only recommendations and medications Medical routine will receive their own, will be divided. The whole grains of the linseed were cleaned and milled and packed in 250 grams of plaster packed with a 30-gram unit. Patients were given a daily dose of one piece of flaxseed powder in a glass of cold water Mix and eat after breakfast.

Main outcome variables

Metabolic parameters (TG, TC, FBS) Cytokines (TNF- α , IFN-g, IL-1 β , IL-6, IL-10, TGF- β) and adipokines (resistin, visfatin) Expression of TLR4 Anthropometric characteristics

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180311039043N1**

Registration date: **2018-12-31, 1397/10/10**

Registration timing: **registered_while_recruiting**

Last update: **2018-12-31, 1397/10/10**

Update count: **0**

Registration date

2018-12-31, 1397/10/10

Registrant information

Name

Nava Morshedzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2235 7484

Email address

nava.morshedzadeh@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-20, 1397/05/29

Expected recruitment end date

2019-07-20, 1398/04/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of flaxseed consumption and flax oil supplement on serum levels of inflammatory markers, adipokines, and components of metabolic syndrome and severity of disease in patients with ulcerative colitis

Public title

Effects of flaxseed consumption and flax oil supplement on serum levels of inflammatory markers, adipokines, and components of metabolic syndrome and severity of disease in patients with ulcerative colitis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age: 18 -55 years The body mass index (BMI) 20 and above Ulcerative colitis, confirmed by histopathology Mild to moderate ulcerative colitis. willingness to cooperate in this project Failure to change the type and dose of medication during the last 3 months.

Exclusion criteria:**Age**

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

Gender

Both

Phase

3

Groups that have been masked

- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

The order of entering people into groups is simple. According to the order of entry of patients into the study, they are assigned to 3 groups: the first patient in the first group, the second patient in the second group, the third patient in the third group, the fourth patient in the first group, and ...

Blinding (investigator's opinion)

Single blinded

Blinding description

The data analyst and clinical physician are not aware of the distribution of patients in the three study groups

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

No.2 Shahid Beheshti University of Medical Sciences, Arabi Ave, Daneshjoo Blvd, Velenjak

City

Tehran

Province

Tehran

Postal code

19839-63113

Approval date

2017-04-21, 1396/02/01

Ethics committee reference number

IR.SBMU.nnftri.Rec.1396.133

Health conditions studied**1****Description of health condition studied**

کولیت اولسراتیو

ICD-10 code

K51

ICD-10 code description

Ulcerative colitis

Primary outcomes**1****Description**

severity of disease

Timepoint

3 months

Method of measurement

Mayo Score / Disease Activity Index (DAI) questionnaire

Secondary outcomes**1****Description**

Plasma glucose

Timepoint

3 months

Method of measurement

laboratory kit

2**Description**

Triglyceride
Timepoint
3 months
Method of measurement
laboratory kit

3

Description
TNF α
Timepoint
3 months
Method of measurement
ELISA

4

Description
IFN- γ
Timepoint
3 months
Method of measurement
ELISA

5

Description
IL-6
Timepoint
3 months
Method of measurement
ELISA

6

Description
IL-1 β
Timepoint
3 months
Method of measurement
ELISA

7

Description
TGF- β
Timepoint
3 months
Method of measurement
ELISA

8

Description
visfatin
Timepoint
3 months
Method of measurement
ELISA

9

Description
Resistin

Timepoint
3 months
Method of measurement
ELISA

Intervention groups

1

Description
Intervention group: take 7 gram flaxseed oil (group A)
Category
Treatment - Drugs

2

Description
Intervention group: 30 gram ground flaxseed (group B)
Category
Treatment - Drugs

3

Description
Control group: Comparison group- without receiving any supplements
Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center

The Gastroenterology Clinic of Taleghani Hospital, Tehran.

Full name of responsible person

Nava Morshedzadeh

Street address

Ayatollah Taleghani Hospital, Yemen Street, Shahid Chamran Highway

City

Tehran

Province

Tehran

Postal code

1985711151

Phone

+98 21 2243 2569

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

Esmat Naseri

Street address

No.2 Shahid Beheshti University of Medical Sciences,
Arabi Ave, Daneshjoo Blvd, Velenjak

City

Tehran

Province

Tehran

Postal code

19839-63113

Phone

+98 21 23871

Email

nasserj_esm@yahoo.com

Grant name**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

Student

Latest degree

Master

Other areas of specialty/work

Nutrition

Street address

No.2 Shahid Beheshti University of Medical Sciences,
Arabi Ave, Daneshjoo Blvd, Velenjak

City

Tehran

Province

Tehran

Postal code

19839-63113

Phone

+98 21 2243 9770

Email

n.morshedzadeh@yahoo.com

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Nava Morshedzadeh

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n.morshedzadeh@yahoo.com

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

Shahid Beheshti University of Medical Sciences

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Nava Morshedzadeh

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Email

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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

No more 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

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Not applicable