Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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-1β, 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 offlaxseed ; 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-1β, 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
TNFα
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
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1985711151
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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

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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
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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
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