Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effects of combined Mediterranean, gluten-free, lactose-free and low-FODMAPs (fermentable oligosaccharides, disaccharides, monosaccharides and polyols) diets accompanied with supplemental formula, and with the consumption of turmeric on quality of life, disease activity index and serum level of some inflammatory factors and oxidative stress in patients with ulcerative colitis.

Protocol summary

Study aim

The effects of combined Mediterranean, gluten-free, lactose-free and low-FODMAP(fermentable oligosaccharides, disaccharides, monosaccharides and polyols) diets accompanied with supplemental formula, and with the consumption of turmeric on patients with ulcerative colitis.

Design

This research is a randomized clinical trial on 50 patients.

Settings and conduct

Anthropometric characteristics are calculated from patients with ulcerative colitis at the beginning and end of the study. Also, at the beginning and end of the study, the quality of life questionnaire(IBDQ-9) and the colitis clinical activity index questionnaire(SCCAIQ) are completed for each patient, and 5 cc of blood is taken after 12 hours of fasting to measure the inflammatory factors.Patients receive the diet for 6 weeks according to the group they belong to.

Participants/Inclusion and exclusion criteria

Entry:The duration of the disease is less than two years, The disease is active in a mild to moderate stage,Not suffering from other diseases,Not using supplement in the past month, BMI over 18.5 and under 30, Age 18 years and above, No change in the type and dosage of the drug consumed during the past month non-entry: Recurrence of the disease,The presence of abscesses or abdominal fistulas, A history of ileostomy and colostomy, Pregnancy or breastfeeding in women, Receiving tube or intravenous feeding, Following special diets and vegetarianism during the last 3 months

Intervention groups

1-intervention group(combined prescription of Mediterranean diets, gluten-free, lactose-free, containing small amounts of fermentable carbohydrates with the Supplementary consumption of 25% of energy from formula and consumption of turmeric for 6 weeks) 2-the control group (usual diet for 6 weeks).

Main outcome variables

TNF-α,hs-CRP,Total AntiOxidative Capacity,quality of life and relapse of the disease will be assessed.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100524004010N38**
Registration date: **2023-04-25, 1402/02/05**
Registration timing: **registered_while_recruiting**

Last update: **2023-04-25, 1402/02/05**
Update count: **0**

Registration date

2023-04-25, 1402/02/05

Registrant information

Name

Azita Hekmatdoost

Name of organization / entity

Shahid Beheshti University of Medical Sciences, National Institute of Nutrition Research

Country

Iran (Islamic Republic of)

Phone

+98 21 2293 0824

Email address

hekmat@sina.tums.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-04-21, 1402/02/01
Expected recruitment end date
2023-10-21, 1402/07/29
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effects of combined Mediterranean, gluten-free, lactose-free and low-FODMAPs (fermentable oligosaccharides, disaccharides, monosaccharides and polyols) diets accompanied with supplemental formula, and with the consumption of turmeric on quality of life, disease activity index and serum level of some inflammatory factors and oxidative stress in patients with ulcerative colitis.

Public title
The effects of combined Mediterranean, gluten-free, lactose-free and low-FODMAP diets accompanied with supplemental formula, and with the consumption of turmeric in patients with ulcerative colitis.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Samples with inflammatory bowel disease confirmed by histopathology The duration of the disease is less than two years The disease is active in a mild to moderate stage (diagnosis of the severity of the disease is the responsibility of the treating physician) Not consuming alcohol and drugs Not suffering from other diseases and intestinal disorders, known autoimmune diseases, cancer, inflammatory and infectious diseases Not using multivitamin-mineral, omega-3, polyphenolic and antioxidant supplements, probiotics as well as the non-use of anticoagulants such as heparin and warfarin, NSAIDs such as ibuprofen, aspirin and diclofenac, antihistamines and calcium channel antagonists such as nifedipine in the past month BMI over 18.5 and under 30 Age 18 years and above No change in the type and dosage of the drug consumed during the past month Not having clinically diagnosed psychiatric disorders that impair the patient's ability to provide written informed consent Willingness to participate in the study
Exclusion criteria:
Recurrence of the disease in a way that leads to the hospitalization of the patient Suffering from other diseases such as biliary disease, kidney diseases, known autoimmune diseases, cancer and liver disorders The presence of abscesses or abdominal fistulas A history of ileostomy and colostomy Pregnancy or breastfeeding in women or Using birth control pills Receiving tube or intravenous feeding Following special diets and vegetarianism during the last 3 months Unwillingness to continue cooperation
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
The method used in this study to create a randomization process is simple randomization, so we utilize random number table. Beginning of the study, each person is randomly assigned to one of the 2 study groups using random number generator software.
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 National Nutrition and Food Technology Research Institute (NNFTRI)
Street address
#7, Shahid Hafezi Ave, Farahzadi Blvd, Shahrak Gharb
City
Tehran
Province
Tehran
Postal code
1981619573
Approval date
2023-03-11, 1401/12/20
Ethics committee reference number
IR.SBMU.NNFTRI.REC.1402.001

Health conditions studied

1

Description of health condition studied

ulcerative colitis

ICD-10 code

K51.9

ICD-10 code description

Ulcerative colitis, unspecified

Primary outcomes

1

Description

serum hs-CRP

Timepoint

At the first of research and end of research(6th week)

Method of measurement

Elisa

2

Description

TNF-α

Timepoint

At the first of research and end of research(6th week)

Method of measurement

Elisa

3

Description

TAC

Timepoint

At the first of research and end of research(6th week)

Method of measurement

Elisa

4

Description

Life Quality

Timepoint

At the first of research and end of research(6th week)

Method of measurement

Questionnaire

5

Description

Disease Activity Index

Timepoint

At the first of research and end of research(6th week)

Method of measurement

Questionnaire

Secondary outcomes

1

Description

Weight

Timepoint

At the first of research and end of research(6th week)

Method of measurement

scale

2

Description

BMI

Timepoint

At the first of research and end of research(6th week)

Method of measurement

Calculation

Intervention groups

1

Description

Intervention group: After calculating the amount of calories needed by each person using the Meflin formula, a diet with 75% of the calories needed to maintain weight is set based on the principles of the Mediterranean diet, gluten-free, lactose-free, low FODMAP and turmeric consumption. The remaining 25% is provided by standard formulas for 6 weeks.

Category

Treatment - Other

2

Description

Control group: After calculating the amount of calories needed by each person, using the Mefflin formula, the usual food plan is adjusted according to the calories needed to maintain weight for 6 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Office of Dr.Nasser Ebrahimi Daryani

Full name of responsible person

Dr.Nasser Ebrahimi Daryani

Street address

No.84, Valiasr St. , Naseri alley

City

Tehran

Province

Tehran

Postal code

1985711151

Phone

+98 21 8879 9446

Email

behnaznarimani1378@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Azita Hekmatdoost
Street address
No.7,West Arghavan Ave.,Farahzad Blvd.,Qods Town
City
Tehran
Province
Tehran
Postal code
1981619573
Phone
+98 21 2235 7483
Email
a_hekmat2000@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
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
Azita Hekmatdoost
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
No. 7, West Arghavan Ave., Farahzadi Blvd., Qods Town
City
Tehran
Province
Tehran
Postal code
1981619573
Phone
+98 21 2235 7483
Email
a_hekmat2000@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Azita Hekmatdoost
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
No. 7, West Arghavan Ave., Farahzadi Blvd., Qods Town
City
Tehran
Province
Tehran
Postal code
1981619573
Phone
+98 21 2235 7483
Email
a_hekmat2000@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Azita Hekmatdoost
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
No. 7, West Arghavan Ave., Farahzadi Blvd., Qods Town
City
Tehran
Province
Tehran
Postal code
1981619573
Phone
+98 21 2293 0824
Fax
Email
a_hekmat2000@yahoo.com
Web page address

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

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available