Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of Lactobacillus paracasei post biotic combination with low FODMAP diet on quality of life, disease activity index and serum level of some inflammatory factors in patients with active mild to moderate ulcerative colitis.

Protocol summary

Study aim
The effect of Lactobacillus paracasei post biotic combination with low FODMAP diet on quality of life, disease activity index and serum level of some inflammatory factors in patients with active mild to moderate ulcerative colitis.

Design
This research is a randomized clinical trial .

Settings and conduct
The study will be conducted at the Gastroenterology and Hepatology Clinic of Tehran. Eligible patients will participate in the study after the inclusion and exclusion criteria are confirmed by a gastroenterology and hepatology specialist and informed consent is obtained. Initial patient information will be recorded and then randomly assigned to two intervention groups (Lewodamp regimen and postobiotic supplement) and control (Lewodamp regimen and placebo). Patients will be followed up for 12 weeks at 4-week intervals in terms of symptom severity, quality of life, and adherence to the regimen. The study will be conducted in a double-blind manner.

Participants/Inclusion and exclusion criteria
Samples' inflammatory bowel disease should be confirmed Histopathologically The duration of the disease should be less than two years. The disease should be mild to moderate (the severity of the disease is determined by the treating physician). Patient's BMI should be above 18.5 and below 30 Willingness to collaborate in this project Age18 and more

Intervention groups
Intervention group (combined prescription of a low-fermentable carbohydrate diet with postbiotic supplementation for 12 weeks) 2- Control group (low-fermentable carbohydrate diet with placebo for 12 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: **IRCT20100524004010N45**
Registration date: **2026-05-30, 1405/03/09**
Registration timing: **registered_while_recruiting**

Last update: **2026-05-30, 1405/03/09**
Update count: **0**

Registration date
2026-05-30, 1405/03/09

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
2026-05-22, 1405/03/01

Expected recruitment end date
2026-10-23, 1405/08/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of Lactobacillus paracasei post biotic combination with low FODMAP diet on quality of life, disease activity index and serum level of some inflammatory factors in patients with active mild to moderate ulcerative colitis.

Public title
The effect of Lactobacillus paracasei post biotic combination with low FODMAP diet on ulcerative colotis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Samples' inflammatory bowel disease should be confirmed Histopathologically The duration of the disease should be less than two years. The disease should be mild to moderate (the severity of the disease is determined by the treating physician). Patient's BMI should be above 18.5 and below 30 Willingness to collaborate in this project Age18 and more
Exclusion criteria:
Recurrence of the disease in a way that leads to hospitalization of the person. Having other diseases such as billiary disease, kidney disease, known autoimmune diseases, cancer, and liver disorders Presence of an abdominal abscess or fistula History of ileostomy and colostomy Pregnancy or breastfeeding in women or use contraceptives History of enteral or parenteral nutrition Fiber, omega-3, and antioxidant supplement consumption in the past 3 months Following special diet and vegan diet within the past 3 months multivitamin mineral and probiotic supplements consumption Anticoagulants such as heparin and warfarin, nonsteroidal anti-inflammatory drugs such as ibuprofen, aspirin and diclofenac, antihistamines and calcium channel antagonists such as nifedipine consumption within the past 1 month Change in the type and dose of medication taken within the past 1 month Alcohol and drug abuse
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample size
Target sample size: **22**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients are randomly assigned to two treatment groups and a control group using a randomized block allocation method. One group is given a postbiotic capsule and the control group is given a placebo. These two groups are poured into identical containers by someone other than the researchers and labeled A and B on the containers. The researchers will not know about this grouping until the end of the study. For this purpose, patients are classified based on BMI and gender, which are confounding factors that we want to be similar between the two groups, and then we randomly assign individuals in each category to the dietary supplement group and the placebo group according to blocks of 6. This method makes the two study groups similar in terms of gender.
Blinding (investigator's opinion)
Double blinded
Blinding description
Patients won’t know if they are receiving the postbiotic or a placebo for double-blinding the study, the bottles containing the relevant capsules will be concealed as A and B by a third person at the beginning of the study, and none of the research team members will know the type of capsule received by each group.
Placebo
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
2026-04-18, 1405/01/29
Ethics committee reference number
IR.SBMU.NNFTRI.REC.1405.016

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
TNF-α
Timepoint
At the first of research and end of research(8th week)
Method of measurement
Elisa

2

Description
Life Quality
Timepoint
At the first of research and end of research(8th week)
Method of measurement
IBDQ-9 Questionnaire

3

Description
Disease Activity Index
Timepoint
At the first of research and end of research(8th week)
Method of measurement
Questionnaire

Secondary outcomes

1

Description
Weight
Timepoint
At the first of research and end of research(8th week)
Method of measurement
scale

2

Description
BMI
Timepoint
At the first of research and end of research(8th week)
Method of measurement
Calculation

3

Description
hs-CRP
Timepoint
At the first of research and end of research(8th week)
Method of measurement
ELISA kit

4

Description
TAC
Timepoint
At the first of research and end of research(8th week)
Method of measurement
ELISA

Intervention groups

1

Description
Intervention group: 50 mg postbiotic supplement with concentration of 10000000000 /gr per day.The supplement is produced in National Nutrition & Food Technology Research Institute, and encapsulated. The patient should take one capsule per day with breakfast.
Category
Treatment - Drugs

2

Description
Control group: 50 mg placebo containing maltodexterin. The supplement is encapsulated in capsules similar to supplements. The patient should take one capsule per day with breakfast.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Behbood Gastroenterology and Hepatology Clinic
Full name of responsible person
Azita Hekmatdoost
Street address
Behbood Gastroenterology and Hepatology Clinic, No. 2, Corner of Alley 14, Beginning of North Mofatteh, Shahid Beheshti Street**
City
Tehran
Province
Tehran
Postal code
1985717413
Phone
+98 21 8817 1901
Email
info@clinicbehbood.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
Street address
Deputy of Research & Technology, Shahid Beheshti University of Medical Sciences, Velenjak
City
Tehran
Province
Tehran
Postal code
1981619573
Phone
+98 21 23871
Email
a_hekmat2000@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
Azita Hekmatdoost
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
No 7, Shahid Hafezi Ave, Farahzadi Blvd, Western 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, Shahid Hafezi Ave, Farahzadi Blvd, Western Qods Town
City
Tehran
Province
Tehran
Postal code
1981619573
Phone
+98 21 2293 0824
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, Shahid Hafezi Ave, Farahzadi Blvd, Western Qods Town
City
Tehran
Province
Tehran
Postal code
1981619573
Phone
+98 21 2293 0824
Email
a_hekmat2000@yahoo.com

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