Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jul 2026

The effect of bromelain supplementation on disease activity and quality of life in patients with inflammatory bowel disease

Protocol summary

Study aim

Determining the effect of bromelain supplementation on disease activity and quality of life in patients with inflammatory bowel disease

Design

A clinical trial with a control group, parallel groups, triple blind, randomized on 84 patients.

Settings and conduct

The study will be conducted in a triple-blind manner (patient, therapist and analyst) in Hazrat Rasool Akram Hospital. People's food intake is evaluated with a 24-hour recal. Scores of disease activity questionnaires in ulcerative colitis and Crohn's disease, quality of life and international physical activity will be evaluated before and after the intervention. Stool samples will be taken from patients before and after the intervention. Nutrient analysis will be done using N4 software.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Having mild to moderate disease activity in ulcerative colitis and mild to moderate disease activity in Crohn's; Minimum age of 18 years and maximum of 70 years Exclusion criteria: The use of anticoagulants, anti-tumor necrosis factor-alpha drugs, steroidal and non-steroidal anti-inflammatory drugs, antibiotics, fiber, and probiotics within two weeks prior to the intervention, pregnancy and lactation, as well as any diseases that may confound the results.

Intervention groups

Intervention group: They will receive two 500 (gdu) capsules containing bromelain manufactured by Salamat Parmon Amin Pharmaceutical Company 1 hour before or 2 hours after food for 8 weeks. Control group: They will receive two 500 mg capsules containing maltodextrin manufactured by Salamat Parmon Amin Pharmaceutical Company 1 hour before or 2 hours after food for 8 weeks.

Main outcome variables

Ulcerative colitis and Crohn's disease activity and Quality of life in inflammatory bowel disease

General information

Reason for update

Due to the high costs of measuring fecal calprotectin, the lack of necessary cooperation by laboratories, and the few laboratories that measure the aforementioned factor, and considering that this factor was not the main outcome of the present study and the sample size was not calculated accordingly, with the opinion of the respected professors of the Nutrition Department and receipt of research approval, as well as adjustment of the study entry and exit criteria with the opinion of the respected consulting physician, this update is required to fully align the information with the updated version of the proposal in the Research Assistant system.

Acronym

IRCT registration information

IRCT registration number: **IRCT20191105045340N2**
Registration date: **2023-07-09, 1402/04/18**
Registration timing: **prospective**

Last update: **2024-12-07, 1403/09/17**
Update count: **1**

Registration date

2023-07-09, 1402/04/18

Registrant information

Name

Seyedeh Tayebeh Rahideh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8670 4843

Email address

rahide.t@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2023-08-01, 1402/05/10
Expected recruitment end date
2024-03-29, 1403/01/10
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of bromelain supplementation on disease activity and quality of life in patients with inflammatory bowel disease

Public title
The effect of bromelain in inflammatory bowel disease
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosis of inflammatory bowel disease based on the diagnosis of a gastroenterologist Having mild to moderate disease activity in ulcerative colitis and mild to moderate disease activity in Crohn's Minimum age of 18 years and maximum of 70 years People express their satisfaction to participate in the study
Exclusion criteria:
Smoking Alcohol consumption in the last 1 month Pregnancy and breastfeeding The consumption of antioxidant supplements such as Vitamin C, Vitamin E, Selenium, Curcumin, Pomegranate Peel, or any other antioxidant supplements in the last 1 month The consumption of anticoagulant drugs The consumption of drugs against tumor necrosis factor alpha The consumption of steroidal and non-steroidal anti-inflammatory agents, antibiotics, fiber, probiotic during the two weeks before the intervention. Patients in the stage of Vitamin D deficiency. Suffering from other chronic inflammatory diseases, mental disorders, or neurological diseases (such as Parkinson's, Alzheimer's, intracranial hemorrhage, head or brain injury), Cushing's syndrome, polycystic ovary syndrome, anemia, hemophilia, leukopenia, thrombocytopenia, asthma, cancer, anorexia nervosa, bulimia nervosa, other autoimmune diseases, and major gastrointestinal surgeries that may affect the condition under study.
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **84**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients meeting the study's inclusion criteria will be allocated to group A or B according to a randomized list generated by the Random Number Calculator software, based on the order of their enrollment. Coordination will be established with Salamat Parmoun Amin pharmaceutical company for the preparation of the placebo. The drug manufacturer will be requested to assign one of the letters (A or B) to the drug and the other to the placebo using a coin toss for randomization.
Blinding (investigator's opinion)
Triple blinded
Blinding description
This interventional study will be conducted in a triple blind manner. Blinding includes patient, therapist and analyst. In order to make a placebo, coordination will be done with Salamat Parmon Amin production company and it is requested that the drug manufacturer put one of the letters A or B on the drug or placebo and the other letter on the other by using a lottery by throwing a coin. The confidentiality of both the drug and placebo types should be maintained until the conclusion of the data analysis, as a fundamental element of the research protocol, and after the analysis, the researcher will ask the person in charge of the drug manufacturing for the type of labels. This means that the therapist will not know the type of medicine or whether the medicine packages are placebo. Neither the patient nor the analyst will know about this. The placebo capsules will bear complete resemblance to the capsules of the intervention group in terms of their coating, color, and smell
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran University of Medical Sciences
Street address
Management of Research Development and Evaluation, Deputy of research and technology, next to Milad Tower, Shahid Hemmat Highway
City
Tehran
Province
Tehran

Postal code
1449614535
Approval date
2023-05-23, 1402/03/02
Ethics committee reference number
IR.IUMS.REC.1402.125

Health conditions studied

1

Description of health condition studied
Crohn's disease
ICD-10 code
K50
ICD-10 code description
Crohn's disease [regional enteritis]

2

Description of health condition studied
Ulcerative colitis
ICD-10 code
K51
ICD-10 code description
Ulcerative colitis

Primary outcomes

1

Description
Ulcerative colitis disease activity questionnaire score
Timepoint
Before the intervention and 8 weeks after the intervention
Method of measurement
Ulcerative Colitis disease Activity Evaluation Questionnaire

2

Description
Crohn disease activity questionnaire score
Timepoint
Before the intervention and 8 weeks after the intervention
Method of measurement
Crohn disease Activity Evaluation Questionnaire

Secondary outcomes

1

Description
Quality of life questionnaire score in inflammatory bowel disease
Timepoint
Before the intervention and 8 weeks after the intervention
Method of measurement
Quality of life assessment questionnaire in inflammatory bowel disease

Intervention groups

1

Description
Intervention group: They will receive 2 capsules of 500 (gdu) containing bromelain manufactured by Salamat Parmon Amin company for 8 weeks, 1 hour before or 2 hours after food.
Category
Treatment - Other

2

Description
Control group: They will receive 2 capsules of 500 mg containing maltodextrin made by Salamat Parmon Amin company for 8 weeks, 1 hour before or 2 hours after food.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Hazrat Rasool Akram Hospital
Full name of responsible person
Seyedeh Tayebeh Rahideh
Street address
Hazrat Rasool Akram Hospital, Corner of Mansouri St., Niayesh St., Sattar Khan St.
City
Tehran
Province
Tehran
Postal code
1445613131
Phone
+98 21 6435 1000
Email
Rasoolhospital@iums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Reza Falak
Street address
The Headquarters of University, Iran University of Medical Sciences, Next to Milad Tower, Hemmat Highway
City
Tehran

Province
Tehran
Postal code
1449614535
Phone
+98 21 8670 3072
Email
rezafalak@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Seyedeh Tayebeh Rahideh
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Department of Nutritional Sciences, Faculty of Health, Iran University of Medical Sciences, Next to Milad Tower, Hemmat Highway
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 8670 4843
Email
tayebeh_rahideh@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Seyedeh Tayebeh Rahideh
Position
Assisstant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Iran University of Medical Sciences, Shahid Hemmat Highway
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 8670 4843
Fax
Email
rahide.t@iums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Seyedeh Tayebeh Rahideh
Position
Assisstant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran, 1449614535, IRAN
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 8670 4843
Fax
Email
tayebeh_rahideh@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