

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)

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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

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Management of Research Development and Evaluation, Deputy of research and technology, next to Milad Tower, Shahid Hemmat Highway

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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 Tayebbeh Rahideh

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Hazrat Rasool Akram Hospital, Corner of Mansouri St., Niayesh St., Sattar Khan St.

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Full name of responsible person

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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

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 Tayebbeh Rahideh

Position

Assistant Professor

Latest degree

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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