Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Jun 2026

The effect of pomegranate peel supplementation on the serum levels of IL-6, IL-10, disease activity index and quality of life in patients with mild to moderate ulcerative colitis: a double-blind clinical trial.

Protocol summary

Study aim

The purpose of this project is to investigate the effect of pomegranate peel supplementation on serum levels of Interleukins 6, 10, disease activity index, and quality of life, and determine and compare the average changes of qualitative and quantitative confounding variables between two groups at the end of the study and within each group at the beginning and end of the study.

Design

A clinical trial with a control group, with parallel groups, double-blind, randomized, on 80 patients. To avoid selection bias, we use the random allocation method, blocks with the Randomization.com website.

Settings and conduct

Patients are diagnosed and informed in Hazrat Rasool Akram and Imam Khomeini Hospitals. Qualified people are divided into the intervention or control group. At the beginning and at the end of the study, after 10-12 hours of fasting, 10 cc of blood will be taken for checking IL-6 and IL-10, and IBDQ-9, IPAQ, P-SCCAI, and three dietary records will be completed. The statistical consultant will prepare the codes from 1 to 80 which will be posted on the supplement packages and envelopes and will be provided to the patients, and no other person will know the type of treatment.

Participants/Inclusion and exclusion criteria

Patients with ulcerative colitis in the mild to moderate stage referring to the specialized clinic of digestive diseases and patients who consent to the disease with an age equal to 18 years, BMI above 18.5, and less than 30 weight (kg2), who are taking special medications with no other specific disease, and do not change their medication dose, activity, and food plan.

Intervention groups

The intervention group and the control group will receive a supplement of 500 mg of dry extract of pomegranate peel or a placebo for eight weeks, respectively.

Main outcome variables

Interleukin 6 serum level; interleukin 10 serum level; disease activity index; Quality of Life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20091114002709N60**
Registration date: **2023-07-01, 1402/04/10**
Registration timing: **registered_while_recruiting**

Last update: **2023-07-01, 1402/04/10**
Update count: **0**

Registration date

2023-07-01, 1402/04/10

Registrant information

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Name of organization / entity

Iran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-25, 1402/04/04

Expected recruitment end date

2024-05-21, 1403/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of pomegranate peel supplementation on the serum levels of IL-6, IL-10, disease activity index and quality of life in patients with mild to moderate ulcerative colitis: a double-blind clinical trial.

Public title

Investigating the effect of pomegranate peel supplement in ulcerative colitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

1. Patient consent to participate in the study 2. Aged 18 years or older (age ≤ 18 years) 3. BMI above 18.5 and less than 30 kg/m2 (30 ≤ BMI ≤ 18.5) 4. Diagnosis of ulcerative colitis by a specialist 5. People with mild to moderate ulcerative colitis according to specialist diagnosis and the Partial Mayo scoring index 6. Users of oral drugs of the 5-aminosalicylic acid group (pentasa, mesalazine or asacol, sulfasalazine) as well as immunomodulatory drugs (azathioprine, methotrexate, prograf, selpest or 6-mercaptopurine).

Exclusion criteria:

1. Changing the type and dosage of the drug used during the last month 2. Pregnant or lactating women 3. Suffering from other diseases, including digestive diseases, autoimmune diseases, cancer, inflammatory and infectious diseases 4. Use of multivitamin-mineral, omega-3, polyphenolic, antioxidants, and herbal supplements during the past month (except for commonly prescribed supplements in ulcerative colitis) 5. Use of corticosteroids, NSAIDs (profen, aspirin and diclofenac), and anti-TNF drugs (Cinnora or Adalimumab, Infliximab or Remicade)

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

This study uses the random allocation method, blocks, to avoid selection bias. For this purpose, the Randomization.com website is used to create blocks. Then, according to the generated sequence, 40 patients were placed in the intervention group and 40 patients in the comparison group

Blinding (investigator's opinion)

Double blinded

Blinding description

Codes 1 to 80 will be prepared by the statistical consultant and stuck on the supplementary packages and their envelopes. Medicine will be placed in closed paper envelopes along with 3 questionnaires as a 24-hour reminder. The doctor, researcher, individual people, and the person who provides the envelopes to the patients are unaware of the type of treatment and only the consultants of the statistical plan know about the codes. At the beginning of the case study, after blood sampling, envelopes are received in the order of numbers and the responsible person writes down the received code and the patient's name. The order of diagnosis of patients for blinding will be provided to statistical consultants until the end of the study, and other people will be unaware of the plan.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committees of Iran university of medical scinces

Street address

Department of Nutrition, School of Public Health, Iran University of Medical Sciences, Tehran, Iran. Shahid Hemmat Highway, 1449614535, Tehran, Iran

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Province

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Postal code

1449614535

Approval date

2023-06-25, 1402/04/04

Ethics committee reference number

IR.IUMS.REC.1402.255

Health conditions studied

1

Description of health condition studied

Inflammatory bowel disease, ulcerative colitis

ICD-10 code

K51

ICD-10 code description

Ulcerative colitis

Primary outcomes

1

Description
Interleukin 6
Timepoint
At the beginning (before starting the intervention) and the end of the study (after the end of the eighth week)
Method of measurement
Blood test

2

Description
Interleukin 10
Timepoint
At the beginning (before starting the intervention) and the end of the study (after the end of the eighth week)
Method of measurement
Blood test

3

Description
Disease activity index
Timepoint
At the beginning (before starting the intervention) and the end of the study (after the end of the eighth week)
Method of measurement
Disease activity index questionnaire

4

Description
Quality of life
Timepoint
At the beginning (before starting the intervention) and the end of the study (after the end of the eighth week)
Method of measurement
IBD quality of life questionnaire

Secondary outcomes

1

Description
Blood pressure
Timepoint
At the beginning (before starting the intervention) and the end of the study (after the end of the eighth week)
Method of measurement
Upper arm blood pressure digital monitor

Intervention groups

1

Description
Intervention group: The group receiving the supplement of 500 mg of dry pomegranate peel extract for eight weeks. In this study, the supplements of Adib Elixir herbal products company with health approval (8975464292723001 IRC:) are used. Pomegranate peel dry extract is produced by this company in capsule cover and 500 mg content.
Category
Treatment - Drugs

2

Description
Control group: The group receiving 500 mg placebo supplement for eight weeks. Placebo capsules are also prepared from Adib Elixir company. These capsules contain 500 mg of medicated corn starch.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Honor Rasool Akram therapeutic educational center
Full name of responsible person
Dr Shahram Agah
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2

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Sponsors / Funding sources

1

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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
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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
According to the additional protocol, the personal information of the candidates is considered confidential.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Anthropometric data, blood variables, and scores of questionnaires used
When the data will become available and for how long
From September, 2024
To whom data/document is available
The presenter and main collaborator
Under which criteria data/document could be used
If the university officially requests
From where data/document is obtainable
The presenter and main collaborator
What processes are involved for a request to access data/document
Official application through the university to the administrator
Comments