

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

Name

Farzad Shidfar

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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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 \leq 18 years) 3. BMI above 18.5 and less than 30 kg/m² ($30 \leq$ BMI \leq 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 sciences
Street address
Department of Nutrition, School of Public Health, Iran University of Medical Sciences, Tehran, Iran. Shahid Hemmat Highway, 1449614535, Tehran, Iran
City
Tehran
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Tehran
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

Street address

Sttar khan - Niyayesh street

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Province

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2

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Foroogh Alborzi

Street address

Imam khomeini hospital- Doctor gharib street- at the end of keshavarz boulevard

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Mohsen Asadi Lari

Street address

School of Medicine, Crossroads of Shahid Hemmat
and Shahid Chamran Expressways

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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

Farzad Shidfar

Position

faculty member

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

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Position

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Latest degree

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Person responsible for updating data

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Full name of responsible person

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Faculty member

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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