Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of Pomegranate peel extract supplement on inflammatory factors and quality of life in Ulcerative Colit patients

Protocol summary

Study aim
Determining the complementary effect of pomegranate peel extract on inflammatory factors and quality of life in patients with ulcerative colitis

Design
Samples are assigned to the voice available and are divided into two equal groups by software and blocking, which are matched in terms of age and gender.

Settings and conduct
Samples are collected and registered in Imam Reza Hospital in Tabriz and examined during two months of intervention. Blinding is done in the researcher and the participants.

Participants/Inclusion and exclusion criteria
Inclusion criteria include a willingness to participate in the study, ages 18 to 70, both male and female, the patient diagnosed by a gastroenterologist, and for two consecutive months the patient's condition is stable. Exclusion criteria include pomegranate allergy, heart disease, diabetes, hepatitis, etc.

Intervention groups
Pomegranate supplement tablets are given to the intervention group as interventions and similar pills, but without pomegranate peel extract, are given to the control group.

Main outcome variables
The effect of pomegranate supplement on inflammatory factors; Effects on fecal calprotectin; Impact on the severity of symptoms; Impact on quality of life; And the effect on anthropometric indicators

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200614047774N1**
Registration date: **2020-09-29, 1399/07/08**
Registration timing: **registered_while_recruiting**
Last update: **2020-09-29, 1399/07/08**
Update count: **0**

Registration date
2020-09-29, 1399/07/08

Registrant information

Name
Majid Keramati

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 31 4634 4017

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majidkeramati87@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-08-22, 1399/06/01

Expected recruitment end date
2020-12-20, 1399/09/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of Pomegranate peel extract supplement on inflammatory factors and quality of life in Ulcerative Colit patients

Public title
The effect of Pomegranate supplement on Ulcerative Colit

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Disease diagnosed by a Gastroenterologist The patient's medical condition has been stable for the past two months The desire to participate in the study
Exclusion criteria:
Sensitivity to pomegranate or its products Pregnancy Lactation Taking steroid drugs, other experimental drugs, and probiotics Kidney, heart and hepatitis Taking other nutritional supplements Having a special diet

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **44**

Randomization (investigator's opinion)
Randomized

Randomization description
Among the patients, according to the criteria of entry and non-entry, 44 patients will be selected as the available sample. The selected individuals are then randomly assigned (using software and blocking) to two intervention groups and a placebo that will be matched in terms of age and gender.

Blinding (investigator's opinion)
Double blinded

Blinding description
To blind the researcher and patients, pomegranate and placebo supplements are divided into groups A and B by a person other than the researcher.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Tabriz University of Medical Sciences

Street address
Jomhoory

City
Jandagh

Province
Isfehan

Postal code
8363136654

Approval date
2020-09-14, 1399/06/24

Ethics committee reference number
IR.TBZMED.REC.1399.658

Health conditions studied

1

Description of health condition studied
Ulcerative Colit

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
IL-6

Timepoint
The beginning and end of the study

Method of measurement
laboratory test

2

Description
IL-10

Timepoint
The beginning and end of the study

Method of measurement
laboratory test

3

Description
TNF-alpha

Timepoint
The beginning and end of the study

Method of measurement
laboratory test

4

Description
hs-CRP

Timepoint
The beginning and end of the study

Method of measurement
laboratory test

5

Description
ANCA

Timepoint
The beginning and end of the study

Method of measurement
laboratory test

6

Description
Fecal Calprotectin
Timepoint
The beginning and end of the study
Method of measurement
laboratory test

Secondary outcomes

1

Description
Quality of life
Timepoint
The beginning and end of the study
Method of measurement
IBDQ-9 questionaire

2

Description
Severity of symptoms
Timepoint
The beginning and end of the study
Method of measurement
SCCAI questionair

3

Description
Antropometric Index
Timepoint
The beginning and end of the study
Method of measurement
Body measurement

Intervention groups

1

Description
Intervention group: 22 patients with ulcerative colitis who will receive two supplements of pomegranate supplements containing 225 mg of dried pomegranate extract for 8 weeks daily after breakfast and lunch. This supplement is from Amin Pharmaceutical Company.
Category
Treatment - Drugs

2

Description
Control group: 22 patients with ulcerative colitis who will receive two pills similar to pomegranate supplement pills daily for 8 weeks but without dried pomegranate peel extract after breakfast and lunch. The platform will be built by Amin Pharmaceutical Company.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Reza hospital
Full name of responsible person
Masuod Faghih Dinevari
Street address
Attar
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majidkeramati87@gmail.com
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr Mohammad Samiei
Street address
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Tabriz Univercity 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
Tabriz University of Medical Sciences
Full name of responsible person
Majid Keramati
Position
Student
Latest degree
Master
Other areas of specialty/work
Nutrition
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Person responsible for updating data

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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
There is no further information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available