

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 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)

###### Phone

+98 31 4634 4017

###### Email address

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**

Isfahan

**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 questionnaire

### **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 Faghieh Dinevari

##### **Street address**

Attar

##### **City**

Tabriz

##### **Province**

East Azarbaijan

##### **Postal code**

8363136654

##### **Phone**

+98 31 4634 4017

##### **Fax**

##### **Email**

majidkeramati87@gmail.com

##### **Web page address**

## **Sponsors / Funding sources**

### **1**

#### **Sponsor**

##### **Name of organization / entity**

Tabriz University of Medical Sciences

##### **Full name of responsible person**

Dr Mohammad Samiei

##### **Street address**

Attar

##### **City**

Tabriz

##### **Province**

East Azarbaijan

##### **Postal code**

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##### **Phone**

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##### **Email**

majidkeramati87@gmail.com

##### **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 scientific 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

### 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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## 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