

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jul 2026

### Evaluation of effect of punica granatum L . (peel)as a supplement on clinical manifestations of ulcerative colitis disease

#### Protocol summary

2014-06-02, 1393/03/12

#### Summary

A - Study population: patients with ulcerative colitis may refer to the Digestive Disease Research Center, Isfahan University of Medical Sciences. Objective: The effect of oral administration of pomegranate peel product on the clinical symptoms of patients with ulcerative colitis, that come to Gastroenterology Research Center, Isfahan University of Medical Sciences in Year 2014. Design of the study: a randomized, double-blind, controlled placebo-controlled, single center, phase II trial. Main criteria for entry: 1. Aged between 18 years and up to 70 years 2. Affected ulcerative colitis Inclusion criteria: patients 18 and up to 70 years old; ulcerative colitis identified by clinical criteria, laboratory and endoscopic disease is confirmed; informed consent. Exclusion criteria: addiction; lack of consent to participate or continue to participate in the study; pregnant women; a history of hypersensitivity to the ingredients of pomegranate; taking prednisone above 15 mg daily and / or cyclosporine and / or infliximab. B - Intervention or interventions studied: administration of products of pomegranate peel (of 6 g as to 8 cc per day) or placebo (combined water and sugar) to patients as syrup. C - Duration of intervention: 28 days D - Primary outcome or consequences of Study: clinical improvement in patients with ulcer colitis

#### Registrant information

##### Name

Mohammad Ali Kamali

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8877 3524

##### Email address

drmkamali@sbmu.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Vice chancellor for research, Shahid Beheshti University of Medical Sciences

#### Expected recruitment start date

2014-05-31, 1393/03/10

#### Expected recruitment end date

2014-06-26, 1393/04/05

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Evaluation of effect of punica granatum L . (peel)as a supplement on clinical manifestations of ulcerative colitis disease

#### Public title

Effect of punica granatum L . (peel) on ulcerative colitis disease

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014040617156N1**

Registration date: **2014-06-02, 1393/03/12**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

Inclusion criteria: patients 18 and up to 70 years old; ulcerative colitis identified by clinical criteria, laboratory and endoscopic disease is confirmed; informed consent. Exclusion criteria: addiction; lack of consent to participate or continue to participate in the study; pregnant women; a history of hypersensitivity to the ingredients of pomegranate; taking prednisone above 15 mg daily and / or cyclosporine and / or infliximab.

**Age**

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

**Gender**

Both

**Phase**

2

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **64**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Double blinded

**Blinding description****Placebo**

Used

**Assignment**

Parallel

**Other design features**

Patients with a score of 4 or greater to 11 Lichtigerr Questionnaire (a validated questionnaire Drsnpjsh clinical symptoms of patients with ulcerative colitis scores from 0 to 21) are examined in this study. The

**Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Shahid Beheshti University of Medical Science

**Street address**

Sixth Floor, College Staff Building Number Two, Shahid Beheshti University of Medical Sciences, next to Taleghani Hospital, Parvaneh St., Yemen St., Shahid Chamran Highway Tehran Tehran Iran, Islamic Republic Of

**City**

Tehran

**Postal code****Approval date**

2013-12-01, 1392/09/10

**Ethics committee reference number**

400/5790

**Health conditions studied****1****Description of health condition studied**

ulcerative colitis

**ICD-10 code**

k51

**ICD-10 code description**

Noninfective enteritis and colitise

**Primary outcomes****1****Description**

Clinical features of patients with ulcerative colitis

**Timepoint**

4 weeks after intervention

**Method of measurement**

Lichtiger Questionnaire

**Secondary outcomes****1****Description**

Side effects

**Timepoint**

4 weeks after the start of the intervention

**Method of measurement**

Patient monitoring

**Intervention groups****1****Description**

Intervention 1: prescription of oral drug products of pomegranate peel as the syrup (containing 6 g of dried pomegranate peel) in two equally divided doses along the 4 weeks, which should be taken one hour before meals. Classification of Intervention: treatment intervention by using the drug. interventions: oral

**Category**

Treatment - Drugs

**2****Description**

Intervention 2: syrup prescribed mix of sugar and water composition in the packaging of food products like pomegranate peel, in total daily 8 cc along 4 weeks, which in two equally divided doses should be taken one hour before meals. category of intervention: intervention with placebo

**Category**

Placebo

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Digestive Disease Research Center, Isfahan University of Medical Sciences

**Full name of responsible person**

Ph.D student of Traditional Medicine. Mohammad Ali Kamali

**Street address**

Digestive Disease Research Center of Isfahan University of Medical Sciences- dr shariatea Ave

**City**

Isfahan

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Vice chancellor for research, Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Dr Afshin Zarghi

**Street address**

No. 8, Shams Alley, Vali Asr St.

**City**

Tehran

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice chancellor for research, Shahid Beheshti University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

*empty*

## Person responsible for general inquiries

**Contact****Name of organization / entity**

School of Traditional Medicine, Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Mohammad Ali Kamali

**Position**

Ph.D student of Traditional Medicine

**Other areas of specialty/work****Street address**

No. 8, Shams Alley, opposite Vali Asr St.

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kamali3030@yahoo.com

**Web page address**

## Person responsible for scientific inquiries

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## Person responsible for updating data

**Contact****Name of organization / entity**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*  
**Study Protocol**  
*empty*  
**Statistical Analysis Plan**  
*empty*  
**Informed Consent Form**  
*empty*

**Clinical Study Report**  
*empty*  
**Analytic Code**  
*empty*  
**Data Dictionary**  
*empty*