

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

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Email address

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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**

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Person responsible for updating data

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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