

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

The effectiveness and non effectiveness of Pantoprazole in the increase of Asacol absorption to treatment of inflammatory bowel disease

Protocol summary

Summary

This study will be done with aim to investigate the effectiveness of Pantoprazole in the increase of Asacol absorption to treatment of inflammatory bowel disease. This study is a single blind clinical trial. The study population will include patients with inflammatory bowel disease (IBD) referred to Imam Reza Hospital in Kermanshah city. The number of 30 eligible patients will be selected and will be assigned in a experimental group of 30 people. The baseline, frequency of defecation and excretion of blood in the feces and drug excretion in the feces will be asked from patients then addition to the routine Asacol, Pantoprazole (40 g once per day) administered for two weeks. After taking the drug for two weeks, frequency of defecation and excretion of blood in the feces and drug excretion in the feces will asked from patients again and will be recorded in the Checklist and changes in the experimental group before and after administration of the drug will be compared. Inclusion criteria: Age between 17 to 70 years; Patients who are taking Asacol medicine tablets (400 g); Patients who have a history of drug excretion. Exclusion criteria: Patients with a history of underlying disease and hypertension drug users; Patients who are contraindicated for Asacol

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017012227761N3**
Registration date: **2017-02-05, 1395/11/17**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-02-05, 1395/11/17

Registrant information

Name

homayoon bashiri

Name of organization / entity

kermanshah university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 3427 6310

Email address

h.bashiri@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kermanshah University of Medical Sciences

Expected recruitment start date

2017-02-08, 1395/11/20

Expected recruitment end date

2017-03-10, 1395/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness and non effectiveness of Pantoprazole in the increase of Asacol absorption to treatment of inflammatory bowel disease

Public title

Effect of Pantoprazole on Asacol absorption in patients with Inflammatory Bowel Disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age between 17 to 70 years; Patients who are taking Asacol medicine tablets (400 g); Patients

who have a history of drug excretion. Exclusion criteria: Patients with a history of underlying disease and hypertension drug users; Patients who are contraindicated for Asacol

Age

From **17 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kermanshah University of Medical Sciences

Street address

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

City

Kermanshah

Postal code

Approval date

2015-06-23, 1394/04/02

Ethics committee reference number

kums.rec.1394.31

Health conditions studied

1

Description of health condition studied

Inflammatory bowel disease

ICD-10 code

K51

ICD-10 code description

Ulcerative colitis

Primary outcomes

1

Description

Asacol absorption

Timepoint

Baseline, the end of the study (two weeks after drug administration)

Method of measurement

Based on Checklist

Secondary outcomes

empty

Intervention groups

1

Description

In experimental group addition to the routine Asacol, Pantoprazole (40 g once per day) administered for two weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza Hospital

Full name of responsible person

Sara Ghadimi noran

Street address

Emam Reza Hospital, Parastar Boulevard

City

Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Kermanshah University of Medical Sciences

Full name of responsible person

Korosh Hamzehee

Street address

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

City

Kermanshah

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, Kermanshah 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**

Kermanshah University of Medical Sciences

Full name of responsible person

Sara Ghadimi noran

Position

Resident of Internal

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Web page address**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