# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

09 Jun 2026

## Combined oral and topical 5-ASA versus topical 5-ASA for the treatment of ulcerative proctitis.

## Protocol summary

**Summary**

1- Objectives: Offering treatments with better performance and fewer side effects in patients with ulcerative proctitis. 2- Design: This is a clinical trial that will be performed in Health Centers of the Babol University of Medical Science. All of the patients will be selected based on both inclusion and exclusion criterias. 3- Setting and conduct: Before starting the study of each case a complete historical and physical examination as well as laboratory tests such as CBC, Cr, LFT and U/A will be done. The patients are randomly divided to two groups with 30 patients in each. 4- Participants including major eligibility criteria: Inclusion criteria:pateints older than 15 years old that have ulcerative colitis upon endoscopic and histologic criteria; severity of disease should be at least 3 of 12. Exclusion criteria:hypersensitivity to salicilate ; active PUD; important liver,renal or heart disease; patients not respond to 5-ASA and on maintenance therapy with 5-ASA . 5- Intervention: The patients of the intervention group are treated by 1 g Mesalasine suppository daily while the control group will be treated by both 3 g oral Mesalasine and 1 g Mesalasine suppository each day. The patients will be visited after four weeks of staring the study. Then, the screening will be continued every 3 mounts until 1 year. 6- Main outcome variables:clinical, endoscopic, and histopathologic response to each treatment strategies.

## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT201604307080N3**
Registration date: **2016-10-25, 1395/08/04**
Registration timing: **retrospective**

Last update:
Update count: **0**

**Registration date**

2016-10-25, 1395/08/04

**Registrant information**

**Name**
Javad Shokri Shirvani
**Name of organization / entity**
Babol University of Medical Sciences
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**Recruitment status**

**Recruitment complete**

**Funding source**

university funding sources

**Expected recruitment start date**

2014-12-21, 1393/09/30

**Expected recruitment end date**

2016-09-20, 1395/06/30

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Combined oral and topical 5-ASA versus topical 5-ASA for the treatment of ulcerative proctitis.

**Public title**

Effect of mesalasine in treatment of distal inflammation of intestine.

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: Pateints older than 15 years old that have ulcerative colitis upon endoscopic and histologic criteria; severity of disease should be at least 3 of 12. Exclusion criteria: Hypersensitivity to salicilate ; Active PUD; Important liver,renal or heart disease; Patients not respond to 5-ASA and on maintenance therapy with 5-ASA.

**Age**
From **15 years** old to **75 years** old

**Gender**
Both

**Phase**
2-3

**Groups that have been masked**
*No information*

**Sample size**
Target sample size: **60**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**

**Blinding (investigator's opinion)**
Not blinded

**Blinding description**

**Placebo**
Not used

**Assignment**
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Ethic committee of Babol University of Medical Sciences

**Street address**
Vice president of research, University of Medical Sciences , Ganjafrooz Street

**City**
Babol

**Postal code**
47176-41367

**Approval date**
2016-01-31, 1394/11/11

**Ethics committee reference number**
MUBABOL.REC.1394.307

## Health conditions studied

### 1

**Description of health condition studied**
Ulcerative Colitis

**ICD-10 code**
K51

**ICD-10 code description**
Crohn disease of large intestine

## Primary outcomes

### 1

**Description**
Clinical response to each therapy groups

**Timepoint**
4 weaks after startin study then every 3 month until 1 year

**Method of measurement**
Disease Activity Index, Simple Clinical Colitis Activity Index Questianaire

### 2

**Description**
Endoscopic response to each therapy groups

**Timepoint**
4 weaks after startin study then every 3 month until 1 year

**Method of measurement**
Disease Activity Index, Simple Clinical Colitis Activity Inde Questianaire

### 3

**Description**
Histopathologic response to each therapy groups

**Timepoint**
4 weaks after startin study then every 3 month until 1 year

**Method of measurement**
Disease Activity Index, Simple Clinical Colitis Activity Index Questianaire

## Secondary outcomes

### 1

**Description**
Drug adverse reaction

**Timepoint**
4 weaks after starting of study then every 3 month until one yesr

**Method of measurement**
Questionnaire

### 2

**Description**
Compliance to each treatment strategy

**Timepoint**
4 weaks after starting of study then every 3 month until one yesr

**Method of measurement**
Questionare

## Intervention groups

### 1

**Description**
Intervention group will be treated with mesalazine suppository500mg twice daily for one year.
**Category**
Treatment - Drugs

### 2

**Description**
Control group will be treated with oral mesalasin 500 mg two tablets three times daily and mesalasin suppositiry 500mg two times daily for one year.
**Category**
Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Ayatollah Rouhani Hospital
**Full name of responsible person**
Aida Ghasempour
**Street address**
Internal Medicine Department, Ayatollah Rohani Hospital, Ganjafrooz street
**City**
Babol

## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Vice Chancellor for research of Babol University of Medical Sciences
**Full name of responsible person**
Ali Bijani
**Street address**
University of Medical Sciences, Ganjafroz Street, Babol
**City**
Babol
**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 of Babol 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**
Babol University of Medical Sciences
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**Position**
Internal Medicine Resident
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## Person responsible for scientific inquiries

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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*