Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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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Iran (Islamic Republic of)
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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
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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
Full name of responsible person
Aida Ghasempour
Position
Internal Medicine Resident
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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