Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of mesalazine in comparison with placebo in uncomplicated diverticulosis with abdominal symptoms

Protocol summary

Summary

In a prospective study of patients who underwent colonoscopy or barium enema due to chronic abdominal pain assessment and are based on clinical symptoms and colonoscopy and radiological diagnosis of diverticulosis for them to be raised and normal abdominal ultrasound, randomly assigned to one of the therapy or placebo-treated groups. Inclusion criteria, individuals 40 to 70 years and exclusion criteria, patients with a history of abdominal surgery, musculoskeletal diseases, spinal cord injury and inflammatory bowel diseases. The number of samples in each group of 60 people and a total of 120 people. In the therapeutic group, a dose of Mesalazine 1.5 gr per day, one week per month, for 3 months and in the placebo group, the placebo for one week per month for 3 months will be used. Doctors and researchers do not know the type of drug. Effectiveness and possible side effects of the medicine is collected on a monthly follow. Patients are followed after treatment, about the relief of abdominal pain, bloating, constipation, mucus discharge(primary outcome) and relapse rate and incidence of diverticulitis and bleeding and complications of treatment (secondary outcome). The two groups will be compared with statistical analysis.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201606237080N4**
Registration date: **2016-07-04, 1395/04/14**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-07-04, 1395/04/14

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

Babol University of Medical Sciences

Expected recruitment start date

2016-06-30, 1395/04/10

Expected recruitment end date

2016-07-31, 1395/05/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of mesalazine in comparison with placebo in uncomplicated diverticulosis with abdominal symptoms

Public title

Treatment of abdominal symptoms in non-complicated

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: the patients between 40 to 70 years old that have chronic abdominal pain and colonoscopy or barium enema are done for them and based on clinical symptoms and colonoscopy and radiology; the diagnosis of diverticulosis is arisen for them. Exclusion criteria: age

below 40 and above 70; patients with history of abdominal surgery; musculoskeletal disease; spinal disorders; gallbladder stone; renal stone; bowel motility disease and inflammatory bowel disease.

Age
From **40 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Triple blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Babol University of Medical Sciences, Deputy of research & technology

Street address
University of Medical Sciences, Ganjafroz Street, Babol

City
Babol

Postal code
4717641367

Approval date
2015-09-08, 1394/06/17

Ethics committee reference number
MUBABOL.REC.1394.142

Health conditions studied

1

Description of health condition studied
diverticulosis

ICD-10 code
k57.3, k57

ICD-10 code description
Diverticular disease of intestine, Diverticular disease of large intestine without perforation or abscess, Diverticular disease of both small and large intestine without perforation or abscess, Diverticular disease of intestine, part unspecified, without

Primary outcomes

1

Description
Bloat

Timepoint
At the start of intervention, 1 month later, 2 months later, 3 months later

Method of measurement
questionnaire

2

Description
Mucus discharge

Timepoint
At the start of intervention, 1 month later, 2 months later, 3 months later

Method of measurement
Number of defecation in a week

3

Description
Constipation

Timepoint
At the start of intervention, 1 month later, 2 months later, 3 months later

Method of measurement
Number of defecation in a week

4

Description
Abdominal pain

Timepoint
At the start of intervention, 1 month later, 2 months later, 3 months later

Method of measurement
VAS(score 0 to 10)

Secondary outcomes

1

Description
Diverticulitis

Timepoint
At the start of the intervention, after 2 month of treatment

Method of measurement
Clinical symptoms and signs and CT scan

2

Description
Bleeding

Timepoint
At the start of the intervention, after 2 month of treatment
Method of measurement
See bleeding

Intervention groups

1

Description
3 Pills of mesalazine 500 mg in a day (1.5 gr daily) for 1 week in each month, for 3 months.
Category
Treatment - Drugs

2

Description
3 pills of placebo, daily, for 1 week in each month, for 3 months.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Health Care Centers of Babol University of Medical Science
Full name of responsible person
Maede Abdinzadeh
Street address
University of Medical Sciences, Ganjafroz Street, Babol
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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
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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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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