

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

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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

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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

Full name of responsible person

Maede Abdinzade

Position

Internal Medicine Resident

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Full name of responsible person

Sohrab Kazemi

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PhD Toxicology

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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