

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Therapeutic effects of low-dose Bismuth subcitrate on symptoms and health-related quality of life in adult patients with irritable bowel syndrome: A clinical trial

Protocol summary

Summary

Irritable bowel syndrome (IBS) is a chronic functional disorder of the gastrointestinal tract that causes abdominal pain or discomfort, and altered bowel with no organic abnormalities. This article is a placebo controlled clinical trial to assess the therapeutic effects of low dose bismuth subcitrate on symptoms and the health-related quality of life in adult patients with IBS. This clinical trial was done in Isfahan, Iran. For each of three subtypes (IBS-C, IBS-D, and IBS-M) we included patients with IBS, diagnosed according to Rome III criteria. They were allocated to placebo (group A) and intervention (group B) consecutively (one to the intervention and one patient to the placebo group) by a non-therapist member of research team. The medication for group B was mebeverine and bismuth subcitrate and for group A was mebeverine and placebo of bismuth subcitrate. With respect to quality of life, the trend of IBS-QOL Score changed significantly during the study period in both intervention and placebo groups. The trends of changes in the severity of pain and bloating during the study among the intervention and control group was significantly different.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017081435691N1**
Registration date: **2017-09-07, 1396/06/16**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-09-07, 1396/06/16

Registrant information

Name

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Name of organization / entity

Isfahan university of medical science

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2015-06-21, 1394/03/31

Expected recruitment end date

2016-01-20, 1394/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Therapeutic effects of low-dose Bismuth subcitrate on symptoms and health-related quality of life in adult patients with irritable bowel syndrome: A clinical trial

Public title

Therapeutic effects of low-dose Bismuth subcitrate on symptoms and health-related quality of life in adult patients with irritable bowel syndrome: A clinical trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Diagnosis irritable bowel syndrome based on Rome 3 criteria; age>18 ; both sex. Exclusion criteria:age<18 and age>70 ; pregnancy; having a documented chronic heart or liver failure; surgery on the gastrointestinal tract except appendectomy; malabsorption diseases; hyperthyroidism; inflammatory bowel diseases; connective tissue diseases; severely progressive diseases, diabetes mellitus; use of antibiotic drugs within a month before the study; significant weight loss; fever; and bloody stools.

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Isfahan Regional Bioethics Committee

Street address

Isfahan University of Medical Sciences

City

isfahan

Postal code

Approval date

2015-08-01, 1394/05/10

Ethics committee reference number

IR.MUI.REC.1392.2.076

Health conditions studied

1

Description of health condition studied

Irritable bowel syndrome

ICD-10 code

k58

ICD-10 code description

irritable colon

2

Description of health condition studied

Irritable bowel syndrome with diarrhea

ICD-10 code

k58.0

ICD-10 code description

Irritable bowel syndrome with diarrhea

3

Description of health condition studied

Irritable bowel syndrome without diarrhea

ICD-10 code

k58.9

ICD-10 code description

Irritable bowel syndrome without diarrhea

Primary outcomes

1

Description

Quality of life

Timepoint

4 month wth monthly follow up

Method of measurement

IBS-qol questionnaire

2

Description

Bloating

Timepoint

4 month wth monthly follow up

Method of measurement

questionare

3

Description

Abdominal pain

Timepoint

4 month wth monthly follow up

Method of measurement

Questionare

4

Description

Satisfaction of defication

Timepoint

4 month wth monthly follow up

Method of measurement

Questionare

5

Description

lbs duration

Timepoint

4 month wth monthly follow up

Method of measurement

questionare

6**Description**

Age

Timepoint

4 month wth monthly follow up

Method of measurement

Questionare

7**Description**

Sex

Timepoint

4 month wth monthly follow up

Method of measurement

Questionare

Secondary outcomes

empty

Intervention groups**1****Description**

The pharmacotherapy regimen for the intervention group was mebeverine hydrochloride 200 mg capsule once daily (before breakfast) and bismuth subcitrate 120 mg tablet twice daily (30 min before breakfast and dinner).

Category

Treatment - Drugs

2**Description**

For the placebo group,mebeverine hydrochloride 200mg capsule once daily(before breakfast) and placebo of bismuth subcitrate(that did not have any effective material) 120 mg tablet twice daily(30 min breakfast and dinner meal)was were given

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

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Full name of responsible person

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2**Recruitment center****Name of recruitment center**

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Full name of responsible person

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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

Isfahan 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**

Isfahan University of Medical Sciences

Full name of responsible person

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Position

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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