

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

Hamed Daghighzadeh

##### Name of organization / entity

Isfahan university of medical science

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3669 3880

##### Email address

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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**

Dr.Hamed Daghighzadeh private clinic

**Full name of responsible person**

Dr.Hamed Daghighzadeh

**Street address**

Dr.Hamed daghighzadeh private clinic, shams abadi St , Isfahan

**City**

Isfahan

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

Dr.Payman Adibi private clinic

**Full name of responsible person**

Dr.Payman Adibi

**Street address**

Dr.Payman adibi private clinic, Shariati St, Isfahan

**City**

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

Isfahan University of Medical Sciences

**Full name of responsible person**

Dr.Payman adibi

**Street address**

Isfahan University of Medical Sciences, Hezarjarib Street, Isfahan

**City**

Isfahan

**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**

Dr.Hamed Daghighzadeh

**Position**

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**Full name of responsible person**

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**Web page address****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*