Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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Hamed Daghaghzadeh
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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 clinica ltrial

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 questionare

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
Ibs 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 Daghaghzadeh private clinic
Full name of responsible person
Dr.Hamed Daghaghzadeh
Street address
Dr.Hamed daghaghzadeh private clinic, shams abadi St , Isfahan
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Isfahan

2

Recruitment center
Name of recruitment center
Dr.Payman Adibi private clinic
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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 Daghaghzadeh
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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