Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Evaluation of the efficacy of Fexofenadine in combination with Mebeverine and Mebeverine with placebo in patients with irritable bowel syndrome

Protocol summary

Study aim
Evaluation of the efficacy of the Fexofenadine as adjunctive therapy to Mebeverine in patients with Irritable bowel syndrome (IBS)

Design
Placebo Controlled Clinical trial (phase 3), Parallel group, Double blind, Randomised

Settings and conduct
In this study, patients suffering from IBS who are admitted to Day hospital, Firoozgar hospital and Municipal's clinic in Tehran and Dr Parsi Clinic in Ahvaz and have the inclusion criteria, will enter to the study. Patients will be divided randomly in two groups. In the intervention group, Fexofenadine tablet 180 mg/day and in control group one placebo tablet a day will be added to the main treatment regimen for 4 weeks. Abdominal pain (severity of pain and Duration of pain),Abdominal distension (bloating,swollen or tight tummy), Satisfaction with fecal excretion, Improving patients symptoms and Quality of life is assessed by the questionnaire before the intervention and one months after the intervention and will be completely reviewed at the end of the study.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1. Patients with Irritable Bowel Syndrome based on Rome IV Criteria 2. Age between 18-65 years old 3. Informed consent. Exclusion criteria: 1. Patients with Diabetes, Cardiovascular Diseases, Neurological and Psychiatric Disorders, Hepatic Disorders, Renal Failure, Celiac and Colitis 2. Pregnancy and Lactation 3. History of Drug Allergy

Intervention groups
In intervention group, patients will receive Mebeverine 200 mg once daily and Fexofenadine tablet 180 mg/day for 4 weeks and in Control group, patients will receive Mebeverine and placebo for 4 weeks.

Main outcome variables
Abdominal pain (severity of pain and duration of pain); Abdominal distension (bloating, swollen or tight tummy); Satisfaction with fecal excretion; The impact of the IBS on the Patient's Quality of Life; Irritable Bowel Syndrome Severity Score

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160813029327N20**
Registration date: **2022-04-26, 1401/02/06**
Registration timing: **registered_while_recruiting**

Last update: **2022-04-26, 1401/02/06**
Update count: **0**

Registration date
2022-04-26, 1401/02/06

Registrant information

Name
Ramin Abrishami

Name of organization / entity
Islamic Azad University, Pharamceutical sciences branch

Country
Iran (Islamic Republic of)

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+98 21 2264 1889

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-04-09, 1401/01/20

Expected recruitment end date

2023-04-09, 1402/01/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the efficacy of Fexofenadine in combination with Mebeverine and Mebeverine with placebo in patients with irritable bowel syndrome

Public title

Studying the effect of Fexofenadine on patients with irritable bowel syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with irritable bowel syndrome based on Rome IV criteria Age between 18-65 years old Informed consent

Exclusion criteria:

Patients with diabetes, cardiovascular diseases, neurological and psychiatric disorders, hepatic disorders, renal failure, Celiac and colitis Pregnancy and lactation History of drug allergy

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Random number table: Two groups of 30 patients were made using simple randomization method, based on Random Sequence Generator via www.random.org website. For Random Allocation concealment, the method of opaque sealed envelopes with random sequence was used. Patients were allocated in one of two groups based on their entry sequence.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study both researcher and patients are not aware which medication the patient is using. Drugs will be dispensed by researcher in uniform packages with codes. Placebo tablets are quite similar in color and shape to the drug.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Islamic Azad University of Tehran Medical Science

Street address

No. 99, The First of Yakhchal Ave., Gholhak, Shariati St.

City

Tehran

Province

Tehran

Postal code

1941933111

Approval date

2019-05-06, 1398/02/16

Ethics committee reference number

IR.IAU.PS.REC.1398.028

Health conditions studied

1

Description of health condition studied

Irritable bowel syndrome

ICD-10 code

K58

ICD-10 code description

Irritable bowel syndrome

Primary outcomes

1

Description

Abdominal Pain (Severity of pain and Duration of pain)

Timepoint

Before intervention and 4 weeks after intervention

Method of measurement

Irritable Bowel Severity Scale (IBSS)

2

Description

Abdominal distension (Bloating, Swollen or Tight tummy)

Timepoint

Before intervention and 4 weeks after intervention

Method of measurement

Irritable Bowel Severity Scale (IBSS)

3

Description

Satisfaction with fecal excretion

Timepoint

Before intervention and 4 weeks after intervention

Method of measurement

Irritable Bowel Severity Scale (IBSS)

4

Description

The impact of the IBS on the Patient's Quality of Life

Timepoint

Before intervention and 4 weeks after intervention

Method of measurement

Irritable Bowel Severity Scale (IBSS)

5

Description

Irritable Bowel Syndrome Severity Score

Timepoint

Before intervention and 4 weeks after intervention

Method of measurement

Irritable Bowel Severity Scale (IBSS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this group, patients will receive Foxofenadine 180 mg tablets produced by Exir Pharmaceutical Company once a day for 4 weeks plus their standard treatment, which is Mebeverine 200 mg capsules produced by Actover Pharmaceutical Company once a day.

Category

Treatment - Drugs

2

Description

Control group: In this group, patients will receive Placebo tablets produced by Exir Pharmaceutical Company once a day for 4 weeks plus their standard treatment, which is Mebeverine 200 mg capsules produced by Actover Pharmaceutical Company once a day.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

DAY general hospital

Full name of responsible person

Fatemeh Koohgard

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Abbaspoor St., Vali Asr Ave

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2

Recruitment center

Name of recruitment center

Tehran District 5 Municipal's Clinic

Full name of responsible person

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At the beginning of Ashrafi Isfahani Street,at the corner of Shali street

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3

Recruitment center

Name of recruitment center

Firoozgar hospital

Full name of responsible person

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Beh afarin street, Karimkhan street, Vali Asr Avenue

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Web page address

https://firoozgar.iums.ac.ir/

4

Recruitment center

Name of recruitment center

Dr. Parsi Clinic

Full name of responsible person

Fatemeh Koohgard
Street address
Arian Doctors Building, East Sharhrivar Street, Kianpars
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
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Phone
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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
Islamic Azad University
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Islamic Azad University
Full name of responsible person
Ramin Abrishami
Position
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Latest degree
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Person responsible for updating data

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Latest degree
A Level or less
Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Information about the primary outcome will be shared after Deidentification of Individual Participant Data

When the data will become available and for how long

after publication of paper,for two years

To whom data/document is available

Academic persons

Under which criteria data/document could be used

Academic or clinical use. users should cite the primary document

From where data/document is obtainable

via email to corresponding author

What processes are involved for a request to access data/document

Submition of valid and formal documentation of affiliation to the Academic Center, Explaination about how to use the information and the purpose of request

Comments