

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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)

Phone

+98 21 2264 1889

Email address

r_abrishami@iaups.ac.ir

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

Street address

Abbaspoor St., Vali Asr Ave

City

Tehran

Province

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Postal code

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Phone

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Fax

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Email

fatemeh.koohgard73@gmail.com

Web page address

<https://www.daygeneralhospital.ir/>

2

Recruitment center

Name of recruitment center

Tehran District 5 Municipal's Clinic

Full name of responsible person

Fatemeh Koohgard

Street address

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

City

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Province

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Postal code

1471778751

Phone

+98 21 4408 1018

Email

fatemeh.koohgard73@gmail.com

3

Recruitment center

Name of recruitment center

Firoozgar hospital

Full name of responsible person

Fatemeh Koohgard

Street address

Beh afarin street, Karimkhan street, Vali Asr Avenue

City

Tehran

Province

Tehran

Postal code

۱۵۹۳۷۴۷۸۱۱

Phone

+98 21 8214 1600

Email

fatemeh.koohgard73@gmail.com

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

City

Ahvaz

Province

Khouzestan

Postal code

6155694854

Phone

+98 61 3336 2787

Email

fatemeh.koohgard73@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Farshad Hashemian

Street address

No. 99, Yakhchal Ave, Shariati St.

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Province

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1941933111

Phone

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Email

fhashemian@yahoo.com

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

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Ramin Abrishami

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

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Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Fatemeh Koohgard

Position

student

Latest degree

A Level or less

Other areas of specialty/work

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Tehran

Postal code

193956466

Phone

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Email

fatemeh.koohgard73@gmail.com

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

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

Comments