Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jun 2026

Effect mirtazapine versus placebo on the treatment of irritable bowel syndrome associated with diarrhea: a double-blind randomized clinical trial

Protocol summary

Study aim

To assess the effect of mirtazapine versus placebo in the treatment of irritable bowel syndrome associated with diarrhea

Design

This is a double-blind randomized clinical trial, phase III, in which 50 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible patients with irritable bowel syndrome associated with diarrhea who will refer to Shahid Beheshti Hospital in Hamadan City during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the block randomization. This trial will be double-blinded so that neither patients nor the physician will examine the patients will be aware of the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 65 years, Irritable bowel syndrome associated with diarrhea Exclusion criteria: Pregnancy or breastfeeding, Taking antidepressants and anxiolytic drugs, Taking anti-diarrhea drugs, History of gastrointestinal surgery except for appendectomy, Diabetes or cardiovascular diseases, Liver or kidney failure, Mental or psychiatric illnesses except for depression and anxiety

Intervention groups

Intervention group: Routine treatment plus mirtazapine tablets 15 mg every night for one week and then 30 mg every night for 6 weeks Control group: Routine treatment plus placebo tablets every night for 7 weeks

Main outcome variables

Primary outcome: Anxiety and depression disorder before the intervention and 7 weeks after that using the Hospital Anxiety and Depression Scale (HADS) The severity of irritable bowel syndrome before the intervention and 7 weeks after that using the irritable bowel syndrome severity Scoring Scale (IBS-SSS) The quality of life before the intervention and 7 weeks after that using the 34-question questionnaire of the irritable bowel syndrome quality of Life (IBS-QoL-34)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N311**
Registration date: **2019-10-21, 1398/07/29**
Registration timing: **prospective**

Last update: **2019-10-21, 1398/07/29**
Update count: **0**

Registration date

2019-10-21, 1398/07/29

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 81 1838 0090

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-22, 1398/09/01

Expected recruitment end date

2020-11-21, 1399/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect mirtazapine versus placebo on the treatment of irritable bowel syndrome associated with diarrhea: a double-blind randomized clinical trial

Public title

Effect mirtazapine versus placebo on the treatment of irritable bowel syndrome associated with diarrhea

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 18 to 65 years, Irritable bowel syndrome associated with diarrhea

Exclusion criteria:

Pregnancy or breastfeeding, Taking antidepressants and anxiolytic drugs, Taking anti-diarrhea drugs, History of gastrointestinal surgery except for appendectomy, Diabetes or cardiovascular diseases, Liver or kidney failure, Mental or psychiatric illnesses except for depression and anxiety

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare four sheets of paper, writing on two sheets the name of the intervention and on the other two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all four sheets are drawn. The four paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.

Blinding (investigator's opinion)

Double blinded

Blinding description

The shape of the medications and placebos will be perfectly the same. Therefore, patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Thus, the trial will be run as double-blind

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2019-09-28, 1398/07/06

Ethics committee reference number

IR.UMSHA.REC.1398.516

Health conditions studied

1

Description of health condition studied

Irritable bowel syndrome with diarrhea

ICD-10 code

K58.0

ICD-10 code description

Irritable bowel syndrome with diarrhea

Primary outcomes

1

Description

Anxiety and depression disorder

Timepoint

Before the intervention and 7 weeks after that

Method of measurement

Using the Hospital Anxiety and Depression Scale (HADS)

2

Description

The severity of irritable bowel syndrome

Timepoint

Before the intervention and 7 weeks after that

Method of measurement

using the irritable bowel syndrome severity Scoring Scale (IBS-SSS)

3

Description

The quality of life

Timepoint

Before the intervention and 7 weeks after that

Method of measurement

Using the 34-question questionnaire of the irritable bowel syndrome quality of Life (IBS-QoL-34)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Routine treatment plus mirtazapine tablets 15 mg every night for one week and then 30 mg every night for 6 weeks

Category

Treatment - Drugs

2

Description

Control group: Routine treatment plus placebo tablets every night for 7 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital in Hamadan city

Full name of responsible person

Shiva Saki

Street address

Shahid Beheshti Hospital, Eram Ave.

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shiva.sky94@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Saeid Bashirian

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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

Hamedan University of Medical Sciences

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

Hamedan University of Medical Sciences

Full name of responsible person

Shiva Saki

Position

Pharmacy Student

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

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Name of organization / entity
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Person responsible for updating data

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Name of organization / entity
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Professor of Epidemiology

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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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