

# 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

##### Email address

poorolajal@umsha.ac.ir

##### 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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School of Pharmacy, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr. Davood Ahmadi Moghadam

**Position**

Pharmacologist

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Medical Pharmacy

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## Person responsible for updating data

**Contact**

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Hamedan University of Medical Sciences

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Dr. Jalal Poorolajal

**Position**

Professor of Epidemiology

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Epidemiology

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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