

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 2026

### Comparison of the effectiveness of sertraline and Nortriptyline on anxiety and gastrointestinal symptoms in patients with irritable bowel syndrome: A double-blind clinical trial study

#### Protocol summary

##### Study aim

Comparison of the effectiveness of Sertraline and Nortriptyline on anxiety and gastrointestinal symptoms in patients with irritable bowel syndrome

##### Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 192 patients. Blocking method will be used for randomization.

##### Settings and conduct

This study is performed in Valiasr Hospital and Bouali Birjand Clinic. 192 patients are randomly divided into three groups receiving sertraline, nortriptyline and antispasmodics. Patients' anxiety and clinical symptoms are assessed by the facilitator at the beginning and one month after the intervention.

##### Participants/Inclusion and exclusion criteria

patients referred to the subspecialty gastroenterology clinic of Bu Ali and Valiasr Hospital in 2021. Inclusion criteria: Patients between the age of 18 to 50 years and also the willingness of patients to participate and Exclusion criteria: Non-cooperation of the patient, history of gastrointestinal cancer and neurological disorders, pregnancy and lactation, bipolar or bipolar patients, contraindications to the use of both Sertraline and Nortriptyline, the use of antidepressants and anti-anxiety drugs, allergies to prescription drugs, concomitant serious physical illnesses such as heart disease, multiple sclerosis, psychosis Like schizophrenia and related disorders, it will be substance abuse and substance abuse.

##### Intervention groups

Intervention groups included patients receiving Sertraline 50 mg, Nortriptyline 25 mg (Abidi Pharmaceutical Company made in Iran) or antispasmodic drug (Maburin at a dose of 135 mg made by Alhavi Company in Iran) and symptomatic treatment of diarrhea or constipation for one month They receive it on a daily

basis.

##### Main outcome variables

Anxiety and clinical signs of patients include: bloating or abdominal distension, bowel movements such as diarrhea or constipation

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190618043934N13**

Registration date: **2021-08-12, 1400/05/21**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-08-12, 1400/05/21**

Update count: **0**

##### Registration date

2021-08-12, 1400/05/21

##### Registrant information

##### Name

Zabihullah Mohaghegh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 56 3232 3232

##### Email address

oabstudent@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-08-06, 1400/05/15

##### Expected recruitment end date

2021-09-06, 1400/06/15

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of the effectiveness of sertraline and Nortriptyline on anxiety and gastrointestinal symptoms in patients with irritable bowel syndrome: A double-blind clinical trial study

**Public title**

Comparison of the effectiveness of sertraline and Nortriptyline on anxiety and gastrointestinal symptoms in patients with irritable bowel syndrome

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Age 18 to 50 years Patient consent to participate in the study

**Exclusion criteria:**

Lack of patient cooperation to participate in further study  
History of gastrointestinal cancer  
History of neurological disorder  
Pregnancy and lactation  
Bipolar or bipolar patients  
Contraindications to the use of two drugs sertraline and nortriptyline  
Use of antidepressants and anti-anxiety drugs  
Allergy to prescription drugs  
Co-occurring with serious physical illnesses such as heart disease, multiple sclerosis  
Having a psychotic illness such as schizophrenia and related disorders  
Substance abuse and substance abuse

**Age**

From **18 years** old to **50 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Outcome assessor

**Sample size**

Target sample size: **192**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Participants in the study will be randomly divided into three intervention groups: sertraline (A), nortriptyline (B) or antispasmodic, and symptomatic treatment of diarrhea or constipation (C) using the blocking method. First, various triple blocks are created using sealed envelopes (ABC, ACB, BAC, BCA, CAB, CBA). One of these blocks is selected randomly and according to the order mentioned in the selected block, patients will be divided into one of three groups A, B or C. Then randomization is performed for other patients in the same way.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Outcome Evaluator: The study facilitator (medical student) will perform the necessary evaluation without knowing the type of medication received by the patients and will be recorded in a checklist designed for this purpose. Patients: The patients participating in the study are not aware of their group, so the drugs are packaged in the same package and given to patients by the pharmacy.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Birjand University of Medical Sciences

**Street address**

Vice Chancellor for Research and Technology, Birjand University of Medical Sciences, Ghaffari Blvd, Birjand Town

**City**

Birjand

**Province**

South Khorasan

**Postal code**

9717811674

**Approval date**

2021-07-12, 1400/04/21

**Ethics committee reference number**

IR.BUMS.REC.1400.117

**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**

Anxiety

**Timepoint**

At the beginning of the study and one month after the start of the intervention in patients

**Method of measurement**

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: The first group in the interventional study are patients who are given sertraline 50 mg daily (Abidi Pharmaceutical Company made in Iran) for one month.

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group: The second intervention group patients who are given nortriptyline 25 mg daily (Abidi Pharmaceutical Company made in Iran) for one month.

#### Category

Treatment - Drugs

### 3

#### Description

Control group: The third intervention group patients who are given antispasmodic medication daily (Moburin with a dose of 135 mg made by Alhawi Company of Iran) and symptomatic treatment of diarrhea or constipation for one month.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Gastroenterology Clinic of Valiasr Hospital\_Birjand

##### Full name of responsible person

Hossein Ehsani

##### Street address

Gastroenterology Clinic of Valiasr Hospital , Ghafari Blvd, Birjand Town

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### 2

#### Recruitment center

##### Name of recruitment center

Bu Ali Birjand Clinic\_Birjand

##### Full name of responsible person

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## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Birjand University of Medical Sciences

##### Full name of responsible person

Dr. Tooba Kazemi

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Vice Chancellor for Research and Technology, Birjand University of Medical Sciences, Ghaffari Blvd, Birjand Town

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research@bums.ac.i

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Birjand 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**

Birjand University of Medical Sciences

**Full name of responsible person**

Zabihullah Mohaghegh

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

General Practitioner

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Birjand University of Medical Sciences

**Full name of responsible person**

Dr. Tahmineh Tavakoli

**Position**

Associate Professor of Internal Medicine and Faculty Member

**Latest degree**

Medical doctor

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Birjand University of Medical Sciences

**Full name of responsible person**

Zabihullah Mohaghegh

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

General Practitioner

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**Web page address**

## 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