

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of anti-anxiety medication (Sertraline and Duloxetine) on anxiety and gastrointestinal symptoms of irritable bowel syndrome patients

Protocol summary

Study aim

Comparison of anti-anxiety drug therapy (duloxetine and sertraline) 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 Buali Gastroenterology Clinic and Valiasr Hospital in Birjand, South Khorasan Province. 192 patients are randomly divided into three groups receiving sertraline, duloxetine 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

Inclusion criteria: Patients between the age of 18 to 50 years; willingness to participate. 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 duloxetine; 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 include patients receiving sertraline 50 mg, duloxetine 60 mg (manufactured by Obaidi Iran) or antispasmodic (135 mg by Alhawi Iran) and symptomatic treatment of diarrhea or constipation for one month. They receive daily.

Main outcome variables

Anxiety and clinical signs of patients include: bloating or abdominal distension, bowel movements in the form of

diarrhea or constipation or diarrhea and constipation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210420051023N1**

Registration date: **2021-09-08, 1400/06/17**

Registration timing: **prospective**

Last update: **2021-09-08, 1400/06/17**

Update count: **0**

Registration date

2021-09-08, 1400/06/17

Registrant information

Name

Enayat Moghri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 56 3242 2111

Email address

moghri1992@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-21, 1400/06/30

Expected recruitment end date

2021-11-20, 1400/08/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of anti-anxiety medication (Sertraline and Duloxetine) on anxiety and gastrointestinal symptoms of irritable bowel syndrome patients

Public title

Effects of Sertralin and Duloxetin in treatment of IBS

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

No receiving psychological therapies before entering the study Not having other structural or functional gastrointestinal disorders at the same time Not suffering from other organic diseases Not having psychotic disorder and personality disorder No risk symptoms such as gastrointestinal bleeding, blood in the stool, fever, weight loss, anemia, nocturnal diarrhea, severe heartburn, etc.,

Exclusion criteria:

Consuming alcohol and substances 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), Duloxetine (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 allocated into one of three groups A, B or C. Then randomization will be 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

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

Moalem

City

Birjand

Province

South Khorasan

Postal code

9۷۱۷۸۵۳۵۷۷

Approval date

2021-06-07, 1400/03/17

Ethics committee reference number

IR.BUMS.REC.1400.070

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**

Depression score in Beck questionnaire

Timepoint

First study and 30 days after the start of sertraline and duloxetine

Method of measurement

Beck Depression Inventory

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Intervention group 1 patients who are given sertraline 50 mg daily (Obidi Pharmaceutical Company made in Iran) for one month.

Category

Treatment - Drugs

2

Description

Intervention group: Intervention group 2 patients who are given duloxetine 60 mg daily (Obidi Pharmaceutical Company made in Iran) for one month.

Category

Treatment - Drugs

3

Description

Control group: Intervention group: 3 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

Buali subspecialty clinic

Full name of responsible person

Tahmineh Tavakoli

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2

Recruitment center

Name of recruitment center

Gastroenterology Clinic of Valiasr Hospital_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

Street address

Moallem Ave., Birjand University of Medical Sciences. Birjand Town

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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

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

Enayat Moghri

Position

Medical Student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Latest degree

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

No - There is not 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

Only part of the data such as information about the main outcome or the like can be shared.

When the data will become available and for how long

Access period starts 3 months after the results are published

To whom data/document is available

Only for researchers working in academic and scientific institutions

Under which criteria data/document could be used

The use of documents is permitted only for use in helping patients

From where data/document is obtainable

enayat moghri

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

Submit a request for the use of documents or data files

Comments