Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of anti-anxiety medication (Sertraline and Duloxetine) on anxiety and gasterointestinal 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, dolextin 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 gasterointestinal 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

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۹۷۱۷۸۵۳۵۷۷

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

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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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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