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

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Iran (Islamic Republic of)

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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

Beck Anxiety Questionnaire

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
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Sponsors / Funding sources

1

Sponsor
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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
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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