Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Jul 2026

Comparison of the effectiveness of anti-anxiety medication (buspirone and sertraline) on anxiety and gastrointestinal symptoms of functional dyspepsia patients

Protocol summary

Study aim
Comparison of the effectiveness of anti-anxiety medication buspirone with sertraline on anxiety and gastrointestinal symptoms of functional dyspepsia patients

Design
Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 141 patients. Blocking method will be used for randomization

Settings and conduct
This study is performed in the hospital of subspecialty gastrointestinal clinics of Birjand city of South Khorasan province. 141 patients are randomly divided into three groups receiving sertraline, buspirone and PPI. Patients' anxiety and clinical symptoms are assessed by the facilitator first, one and three months after the intervention.

Participants/Inclusion and exclusion criteria
Patients will be referred to Birjand gastroenterology clinics in 1400. Inclusion criteria include: consent to participate in the study, not receiving psychological treatment before entering the study, not having other structural or functional gastrointestinal disorders at the same time, keeping the type and amount of drug used during the study if taking drugs, not consuming alcohol And drugs, no psychotic disorder and personality disorder, no risk symptoms such as gastrointestinal bleeding, fever, weight loss, anemia, nocturnal diarrhea, severe heartburn, no other organic disease and exclusion criteria include: having the disorder Simultaneous psychosis or other gastrointestinal disorders are the presence of danger signs in the patient and having complete criteria for personality disorder.

Intervention groups
Intervention groups include patients receiving sertraline 50 mg, buspirone 5 mg every 8 hours and control group receiving PPI treatmen (Abidi Pharmaceutical Company, Iran) daily for three months.

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: **IRCT20210831052349N1**
Registration date: **2021-11-28, 1400/09/07**
Registration timing: **registered_while_recruiting**

Last update: **2021-11-28, 1400/09/07**
Update count: **0**

Registration date
2021-11-28, 1400/09/07

Registrant information

Name
hajar rahmani firoozjaee

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-11-21, 1400/08/30

Expected recruitment end date
2022-01-19, 1400/10/29

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effectiveness of anti-anxiety medication (buspirone and sertraline) on anxiety and gastrointestinal symptoms of functional dyspepsia patients

Public title
Comparison of the effectiveness of anti-anxiety medication (buspirone and sertraline) on anxiety and gastrointestinal symptoms of functional dyspepsia patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Willingness to participate in the study after fully explaining the objectives of the research and the disadvantages and advantages of the methods not receiving psychological therapies before entering the study No alcohol and drugs Absence of danger signs such as gastrointestinal bleeding, blood in the stool, fever, weight loss, anemia, nocturnal diarrhea, severe heartburn No psychotic disorder and personality disorder Possibility to keep the type and amount of drug used during the research period if the drug is used No other organic disease Lack of other structural or functional gastrointestinal disorders
Exclusion criteria:
Having psychotic disorder or other gastrointestinal disorders Existence of danger signs in the patient (such as gastrointestinal bleeding, blood in the stool, fever, weight loss, anemia, nocturnal diarrhea, severe heartburn, etc.) Having complete criteria for personality disorder
Age
From **18 years** old to **50 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **141**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants in the study will be randomly divided into three intervention groups: sertraline (A), buspirone (B) or antispasmodic, and Proton-pump inhibitors (PPI) (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. Data Analyzer: Data is coded to a third party (statistics expert) for analysis and the individual is unaware of the grouping.
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
No.45 ,13 Alley ,Moallem Blvd ,Birjand
City
Birjand
Province
South Khorasan
Postal code
9717865565
Approval date
2021-08-28, 1400/06/06
Ethics committee reference number
IR.BUMS.REC.1400.158

Health conditions studied

1

Description of health condition studied
Functional dyspepsia
ICD-10 code
K30
ICD-10 code description
Functional dyspepsia

Primary outcomes

1

Description
Anxiety score in Beck questionnaire
Timepoint
at the beggining (day 0),day 30,day 90
Method of measurement
Beck anxiety questionnaire

Secondary outcomes

1

Description
Upper gastrointestinal symptoms severity questionnaire PAGI-SYM
Timepoint
At the beggining (day 0), day 30, day 90
Method of measurement
20-item PAGI-SYM symptom severity questionnaire

Intervention groups

1

Description
Intervention group 1 patients who are given sertraline 50 mg daily (Abidi Pharmaceutical Company made in Iran) + PPI drugs for three month.
Category
Treatment - Drugs

2

Description
Intervention group 2 patients who are given Buspirone 5 mg daily (Abidi Pharmaceutical Company made in Iran) + PPI drugs for three month.
Category
Treatment - Drugs

3

Description
Control group: patients who are given antispasmodic medication daily (Moburin with a dose of 135 mg made by Ramopharmin Company of Iran) and symptomatic treatment of diarrhea or constipation for three month.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Valiasr hospital - Gastroenterology Clinic
Full name of responsible person
Tahmanie Tavakoli
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Sponsors / Funding sources

1

Sponsor
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public_r@bums.ac.ir
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
Private
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
Hajar Rahmani Firoozjaee
Position

Medical Student

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no need to publish individual patient information

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