

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

Investigation of the effectiveness of anti-anxiety medication (Buspirone and Mirtazapine) on anxiety and gastrointestinal symptoms of functional dyspepsia patients with postprandial discomfort syndrome

Protocol summary

Study aim

Determining the effectiveness of anti-anxiety drug therapy (buspirone and mirtazapine) on anxiety and gastrointestinal symptoms in patients with functional dyspepsia with symptoms of postprandial discomfort syndrome

Design

A controlled, parallel-group, single-blind, randomized, phase 2-3 clinical trial of 120 patients. Randomization by block method and random unit of patient number

Settings and conduct

This study will be performed in Birjand University of Medical Sciences(gastroenterology clinic)in the fall of 1400.120 patients are divided into 3groups of 40:group(1 receiving buspirone),group(2 mirtazapine)and group(3 control).Each group is treated and monitored with doses of drugs for 1month.Before and at the end of the first month,results are recorded and analyzed.one-blinded - patients have no information about the medication

Participants/Inclusion and exclusion criteria

Inclusion:Age,Willingness to participate•No psychological treatment,other structural or functional gastrointestinal disorders at the same time,other organic disease,alcohol and drug use,personality disorder and psychosis,danger symptoms•Stability of medication;Exclusion:Psychotic disorder or other concomitant GI disorder•personality disorder•Dangerous symptoms•Withdrawal of the patient,Failure to follow recommendations

Intervention groups

120 patients divided into three groups of 40:group (1 buspirone), group (2 mirtazapine) and group (3 control). Each group is treated and monitored with doses of drugs for1month.Before and at the end of the first month, clinical results are recorded and analyzed

Main outcome variables

Functional dyspepsia ; severity of anxiety ; severity of dyspeptic symptoms

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210724051972N1**

Registration date: **2022-12-29, 1401/10/08**

Registration timing: **retrospective**

Last update: **2022-12-29, 1401/10/08**

Update count: **0**

Registration date

2022-12-29, 1401/10/08

Registrant information

Name

Mahdieh Khorashadizade

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 56 3234 0464

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-01, 1400/08/10

Expected recruitment end date

2022-03-01, 1400/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of the effectiveness of anti-anxiety medication (Buspirone and Mirtazapine) on anxiety and gastrointestinal symptoms of functional dyspepsia patients with postprandial discomfort syndrome

Public title

Investigation of the effectiveness of Buspirone and Mirtazapine on functional dyspepsia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Willingness to participate in the study after explaining all the objectives of the research and the advantages and disadvantages of the methods
Failure to receive psychological treatment before entering the study
Lack of other structural or functional gastrointestinal disorders
No other organic disease
Possibility to keep the type and amount of drug used during the research period if the drug is used
No alcohol and drugs
No psychotic disorder and personality disorder
Absence of alarm signs such as gastrointestinal bleeding, blood in the stool, fever, weight loss, anemia, nocturnal diarrhea, severe heartburn
Age between 18 and 50 years

Exclusion criteria:

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

- Participant

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

method of randomization: block unit of randomization:
Number of patients In this study, the randomized block method is used as six blocks with equal proportions of groups (36 different permutations - abcabc, abcacb, abcbca, ..., cabcab) from one to thirty-six numbering and then random selection of blocks are performed using the production of a random number between 1 and 36 The packages are printed and placed in separate envelopes, and according to the order of the person who provides the drug, she provides the desired letter from the drug group or the pharmaceutical form. In this study, we will use the restricted randomization method (blockrandomization). Blocking is usually used in order to create a balance in the number of samples allocated to each of the study groups. This feature helps the researchers so that the number of samples allocated to each of the studied groups is equal. The size of all the blocks is equal and we will have 6 blocks in this three-group experiment. The randomization tool is also from the production software. Random allocation software is used. In addition to simple randomization, these random sequence generation softwares are capable of

generating random sequences using the blocking method. For concealment, we use allocation concealment, which is the method used. It refers to the implementation of random sequence on the participants in the study, so that the allocated group is not known before the allocation of the individual. By using opaque sealed envelopes with random sequence (Sequentially numbered, sealed, opaque envelopes). In this method, each of the random sequences created is recorded on a card and the cards are placed in the letter envelopes in order. In order to maintain a random sequence, the outer surface of the envelopes is numbered in the same order. Finally, the lid of the letter envelopes is glued and placed in a box. At the time of registration of the participants, based on the order in which the eligible participants entered the study, one of the envelopes will be opened and the assigned group of that participant will be revealed.

Blinding (investigator's opinion)

Single blinded

Blinding description

The participants do not know which treatment they will receive, and the referring physician also does not know about the assigned treatment. The person interviewing the patients does not know about the treatment received by the patients. Random allocation list that uses the software Random Allocation Software is produced in random permutation blocks and is available to the assistant, based on which the drugs will be allocated to the diseases in order. It will be explained to the participants that they are in a study and the groups will be introduced and mentioned that they will be randomly assigned to one of the groups. By using opaque sealed envelopes with random sequence (Sequentially numbered, sealed, opaque envelopes). In this method, each of the random sequences created is recorded on a card and the cards are placed in the letter envelopes in order. In order to maintain a random sequence, the outer surface of the envelopes is numbered in the same order. Finally, the lid of the letter envelopes is glued and placed in a box. At the time of registration of the participants, based on the order in which the eligible participants entered the study, one of the envelopes will be opened and the assigned group of that participant will be revealed.

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

Ghafari Ave, Birjand university of medical sciences,
Birjand city

City

Birjand

Province

South Khorasan

Postal code

9717853577

Approval date

2021-09-14, 1400/06/23

Ethics committee reference number

IR.BUMS.REC.1400.204

Health conditions studied

1

Description of health condition studied

Functional dyspepsia

ICD-10 code

K30

ICD-10 code description

Functional dyspepsia,Mirtazapine,Buspirone,Anxiety

Primary outcomes

1

Description

The severity of dyspepsia symptoms in the three groups receiving buspirone, mirtazapine and the control group

Timepoint

The severity of dyspepsia symptoms in the three groups receiving buspirone, mirtazapine before the intervention and one month after the intervention and three months after the intervention and in the control group before the intervention and one month after the intervention

Method of measurement

patient assessment of upper gastrointestinal symptom severity index questionnaire(pagi-sym)

2

Description

Beck anxiety score in three groups receiving buspirone, mirtazapine and control group

Timepoint

Determining and comparing the mean score of Beck anxiety in the two groups receiving buspirone, receiving mirtazapine before the intervention, one month after the intervention and three months after the intervention and in the control group before the intervention and one month after the intervention

Method of measurement

Beck Anxiety Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: First - Buspirone receiving group with a dose of 5 mg three times a day for three months (Buspirax-brand name, Tehrandaroo factory)

Category

Treatment - Drugs

2

Description

Control group: First - group receiving Pantoprazole at a dose of 40 mg daily for three months(Nolpaza-brand name, Actoverco)

Category

N/A

3

Description

Intervention group: Second - the group receiving Mirtazapine at a dose of 7.5 mg nightly for three months (Mirtazapine-brand name)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

One of the affiliated units of Birjand University of Medical Sciences (gastroenterology clinic)

Full name of responsible person

Tahmine Tavakoli

Street address

Gastroenterology Clinic - Taleghani 1 Sepideh
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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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South Khorasan, Birjand, Ghaffari St., Deputy of
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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

Dr Tahmineh Tavakoli

Position

Associate Professor

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for scientific**inquiries****Contact****Name of organization / entity**

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Full name of responsible person

Mahdieh Khorashadizade

Position

stugent- Intern

Latest degree

Bachelor

Other areas of specialty/work

General Practitioner

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Person responsible for updating data**Contact****Name of organization / entity**

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Latest degree

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Other areas of specialty/work

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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 more information

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not 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

Yes - There is 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

Yes - There is a plan to make this available

Title and more details about the data/document

The main outcome of the study

When the data will become available and for how long

One year after the results are published

To whom data/document is available

people working in academic institutions or people working in businesses

Under which criteria data/document could be used

Related researchers in this field

From where data/document is obtainable

Mahdieh Khorashadizade khorashadi.m@yahoo.com

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

Give an email and after checking the applicant's profile, send the information

Comments