

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The effects of Buspirone on patients with functional dyspepsia

Protocol summary

Study aim

Determining the effects of Buspirone on patients with functional dyspepsia referred to gastrointestinal clinics in Sari

Design

This is a randomized double-blind clinical trial with a control group. In this study, 40 Patients with dyspeptic symptoms for at least 3 months and normal endoscopy who will refer to gastrointestinal clinic of Imam Khomeini Hospital of Sari will enter the study. They will be divided into 2 groups with block randomization method. One group will receive tablets of Buspiron 5 mg three times daily during the first month and tablets of Buspiron 10 mg three times daily during the second month. Placebo group patients will receive placebo tablets 3 times daily during the whole 2 months.

Settings and conduct

This is a randomized double-blind clinical trial with a control group. In this study, 40 patients with functional dyspepsia who will refer to gastrointestinal clinic of Imam Khomeini Hospital of Sari during January 2019 until June 2019 will enter the study. They will be divided into 2 groups with block randomization method.

Participants/Inclusion and exclusion criteria

40 Patients with dyspeptic symptoms for at least 3 months and normal endoscopy who will refer to gastrointestinal clinic of Imam Khomeini Hospital of Sari will enter the study.

Intervention groups

The first group of patients will receive Buspirone (5 mg three times daily during the first month and 10 mg three times daily during the second month) and the next group will receive placebo tablets (3 times daily during the whole 2 months).

Main outcome variables

Effects of Buspirone on abdominal bloating induced by functional dyspepsia; Effects of Buspirone on early satiety induced by functional dyspepsia; Effects of Buspirone on post prandial fullness induced by functional dyspepsia; Effects of Buspirone on functional

dyspepsia in comparison to placebo

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180405039198N1**

Registration date: **2019-06-08, 1398/03/18**

Registration timing: **registered_while_recruiting**

Last update: **2019-06-08, 1398/03/18**

Update count: **0**

Registration date

2019-06-08, 1398/03/18

Registrant information

Name

Tarang Taghvaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3311 0099

Email address

tarang_taghvaei@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-22, 1397/10/01

Expected recruitment end date

2019-07-22, 1398/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of Buspirone on patients with functional dyspepsia

Public title

effects of Buspirone on functional dyspepsia

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Having dyspeptic symptoms for at least 3 months Normal upper gastrointestinal endoscopy

Exclusion criteria:

History of psychological diseases History of gastric or esophageal surgery Having Celiac disease

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization was used. so that patients were classified in 5-patients blocks according to their age and gender.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patient and the statistician are blind to the study groups.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Mazandaran University of Medical Sciences

Street address

Amir mazandaranin street

City

Sari

Province

Mazandaran

Postal code

4816613135

Approval date

2018-12-09, 1397/09/18

Ethics committee reference number

IR.MAZUMS.IMAM HOSPITAL.rec.1397.085

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**

Therapeutic effect

Timepoint

Before starting the study and then after two months

Method of measurement

Questionnaire

Secondary outcomes

empty

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

Intervention group: The patients in this group will receive 3 tablets of Buspirone 5 mg (Iran Daru company) daily during the first month and three 10 mg tablets during the second month.

Category

Treatment - Drugs

2**Description**

Control group: The patients in this group will receive 3 placebo tablets daily for 2 months.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam Khomeini Hospital

Full name of responsible person

Tarang Taghvaei

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Amir Mazandarani street

City

Sari

Province

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4816613135

Phone

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Email

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Latest degree

Subspecialist

Other areas of specialty/work

Gastroenterology

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Mazandaran University of Medical Sciences

Full name of responsible person

Dr. Majid Saeidi

Street address

Moallem square

City

Sari

Province

Mazandaran

Postal code

4817844718

Phone

+98 11 3448 4800

Email

majsaeedi@gmail.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Mazandaran 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**

Mazandaran University of Medical Sciences

Full name of responsible person

Tarang Taghvaei

Position

Associate Professor

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

Mazandaran University of Medical Sciences

Full name of responsible person

Tarang Taghvaei

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

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

Mazandaran University of Medical Sciences

Full name of responsible person

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Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

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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