

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 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

**Street address**

Amir Mazandarani street

**City**

Sari

**Province**

Mazandaran

**Postal code**

4816613135

**Phone**

+98 11 3377 1760

**Email**

tarang\_taghvaei@yahoo.com

**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

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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**

Gastroenterology

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**Person responsible for updating data****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**

Gastroenterology

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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