

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the therapeutic effect of buspirone in improving the dysphagia of patients with ineffective esophageal motility

Protocol summary

2021-05-29, 1400/03/08

Study aim

Determining the effect of buspirone in the treatment of dysphagia in patients with ineffective esophageal motility.

Design

Clinical trial, without control group, with parallel groups, double-blind, randomized, phase 3 on 50 patients.

Settings and conduct

Endoscopy section

Participants/Inclusion and exclusion criteria

Inclusion criteria include willingness to participate in the study, age over 18 years and no underlying diseases, and exclusion criteria in patients include cancer, mechanical obstruction, eosinophilic esophagitis, diabetes, opium addiction, collagen vascular disease, muscle disorders and inability to follow up patients.

Intervention groups

Intervention group: Group 1: Patients are prescribed 40 mg of pantoprazole daily for 30 days. Group 2: Patients are prescribed 40 mg of pantoprazole daily, along with 20 mg of buspirone daily for 30 days.

Main outcome variables

Mayo Score Esophageal sphincter (LES) resting pressure
Distal contractile integral pressure Integrated Relaxation Pressure (IRP)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210418051005N1**
Registration date: **2021-05-29, 1400/03/08**
Registration timing: **prospective**

Last update: **2021-05-29, 1400/03/08**

Update count: **0**

Registration date

Registrant information

Name

Foroogh Alborzi Avanaki

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6119 2642

Email address

falborzi@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-05, 1400/03/15

Expected recruitment end date

2022-03-20, 1400/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the therapeutic effect of buspirone in improving the dysphagia of patients with ineffective esophageal motility

Public title

Evaluation of the therapeutic effect of buspirone in improving the dysphagia of patients with ineffective esophageal motility.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Ineffective esophageal motility Age between 18 and 70

Consent Patient with symptom

Exclusion criteria:
Cancer Mechanical obstruction Eosinophilic esophagitis
Diabetes Opium addiction Collagen vascular disease
Muscle disorders

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
4 person blocks Patients are divided into two groups based on a table of random numbers if they go to the endoscopy department to receive medicine; Accordingly, each patient is randomly assigned a number (individual or even). Pantoprazole or a combination of pantoprazole plus buspirone is packaged in similar white bags by the research guide and will be provided to administrators for prescription. The group with odd numbers received the drug combination of pantoprazole plus buspirone, and the other group (even numbers) received the drug pantoprazole. The only person who knows the contents of the envelope is the research guide, and patients, administrators, and outcome assessors are unaware.

Blinding (investigator's opinion)
Double blinded

Blinding description
Medications are given to patients by a trained nurse who is not informed about details of the study. Interpretation of the manometer is done by a specialist who is not informed about details of the study.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Imam Khomeini Hospital Complex, Tehran University of Medical Sciences (Research Ethics Committee

Street address

Imam khomeini Hospital Complex, Keshavarz Blvd, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

1417933791

Approval date

2020-09-02, 1399/06/12

Ethics committee reference number

IR.TUMS.IKHC.REC.1399.181

Health conditions studied

1

Description of health condition studied

Ineffective esophageal motility

ICD-10 code

DA21

ICD-10 code description

Motility disorders of oesophagus

2

Description of health condition studied

Dysphagia

ICD-10 code

R13.1

ICD-10 code description

Dysphagia

Primary outcomes

1

Description

Mayo Score

Timepoint

Before intervention and then after 30 days

Method of measurement

Mayo Score

2

Description

esophageal sphincter (LES) resting pressure

Timepoint

Before intervention and then after 30 days

Method of measurement

Manometer

3

Description

Distal contractile integral pressure

Timepoint

Before intervention and then after 30 days

Method of measurement

Manometer

4

Description

Integrated Relaxation Pressure (IRP)

Timepoint

Before intervention and then after 30 days

Method of measurement

Manometer

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Group 1: Patients are prescribed 40 mg of pantoprazole daily for 30 days.

Category

Treatment - Drugs

2

Description

Intervention group: Group 2: Patients are prescribed 40 mg of pantoprazole daily, along with 20 mg of buspirone daily for 30 days.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam khomai Hospital Complex

Full name of responsible person

Forough Alborzi Avanaki

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Imam Khomai Hospital Complex, Keshavarz Blvd,
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Forough Alborzi Avanaki

Position

Assistant Professor of Gastroenterology and
Hepatology

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

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Position

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Other areas of specialty/work

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Person responsible for updating data

Contact

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Full name of responsible person

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Position

Assistant professor, Fellowship of Liver and gastrointestinal tract

Latest degree

Subspecialist

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is 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

Therapeutic effect of buspirone in improving dysphagia in patients with ineffective esophageal motility

When the data will become available and for how long

"Access period starts 5 months after the results are published"

To whom data/document is available

Academic and scientific persons

Under which criteria data/document could be used

There is no limit to the use of data or documentation due to unidentifiable patient information.

From where data/document is obtainable

Dr Elham Baghereslami

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

After receiving an application via email, it will be answered for one week.

Comments