# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 2026

## Comparison of distal esophageal spasm treatment with Diltiazem vs. Fluoxetine on clinical and monomeric findings

## Protocol summary

**Study aim**
Comparison of Diltiazem with Fluoxetine treatment on clinical and monomeric findings of distal esophageal spasm

**Design**
Parallel group, double blind, randomized, phase 3 controlled trial on 80 patients. GraphPad software will be used for randomization.

**Settings and conduct**
The study will be performed on 80 patients referred to Taleghani Hospital in Tehran with the diagnosis of distal esophageal spasm based on manometry. Patients are divided into 2 groups of 40 people. The first group will be treated with fluoxetine 10 mg daily and omeprazole 20 mg every 12 hours for 2 months and the second group will be treated with diltiazem 30 mg daily and omeprazole 20 mg every 12 hours for 2 months. Completion of questionnaires and esophageal manometry will be done before and 2 months after the start of medication. Due to the apparent similarity of the drugs, the patient does not know the type of drug. The person who responsible for collection of patients' data and questionaries also does not know the type of drug.

**Participants/Inclusion and exclusion criteria**
Age more than 18 years All patients diagnosed as distal esophageal manometry according to manometry

**Intervention groups**
Intervention group 1: Fluoxetine 10 mg daily and omeprazole 20 mg twice daily for 2 months Intervention group 2: Diltiazem 30 mg daily and omeprazole 20 mg twice daily for 2 months

**Main outcome variables**
Improve clinical symptoms (chest pain, dysphagia), improve quality of life, improve findings of esophageal manometry

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20220413054528N1**
Registration date: **2022-06-22, 1401/04/01**
Registration timing: **registered_while_recruiting**

Last update: **2022-06-22, 1401/04/01**
Update count: **0**

**Registration date**
2022-06-22, 1401/04/01

**Registrant information**

**Name**
ahmad ghorbanpour rasekh

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

**Phone**
+98 13 4222 0733

**Email address**
a_g_rassekh@yahoo.com

**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2022-06-22, 1401/04/01

**Expected recruitment end date**
2022-12-22, 1401/10/01

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
Comparison of distal esophageal spasm treatment with Diltiazem vs. Fluoxetine on clinical and monomeric findings

**Public title**
Effect of diltiazem and fluoxetine on DES
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Age more than 18 years All patients diagnosed as distal esophageal manometry according to manometry
**Exclusion criteria:**
1. Patients abusing drugs 2. Patients with systemic disorders including :Mastocytosis Systemic vasculitis, Sarcoidosis, Hypothyroidism, Diabetes mellitus, Fibromyalgia, Adrenal insufficiency, Coeliac disease, inflammatory bowel disease, Hypertension (high blood pressure), Metabolic syndrome, AIDS, Graves' disease, Systemic lupus erythematosus, Rheumatoid arthritis, Atherosclerosis, Sickle cell disease, Myasthenia gravis, Systemic Sclerosis, Sinusitis
**Age**
From **18 years** old
**Gender**
Both

**Phase**
3
**Groups that have been masked**

- Participant
- Outcome assessor

**Sample size**
Target sample size: **80**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
Based on sample size of study, 20 blocks with a size of 4 (such as AABB, ABAB, etc.) in a randomly varied order, will be used for random allocation. Random blocks will be provided by GraphPad software. The blocks will be placed one after the other in sequence, from the first to the 20th of them (equivalent to the first to the 80th patient). For example, if the blocks that will be provided by the software are AABB, BBAA, ABAB, respectively, the order of patients' bowel preparation regimens will be AABBABABBBAA. The order of the blocks (20 provided blocks, it means arranging 80 drug regimens for 80 patients) will be reposed to the clinic secretary. Patients who will be diagnosed distal esophageal spasm based on manometry, and declare their informed consent to enter the study, will receive a drug regimen based on the provided blocks A or B, respectively.
**Blinding (investigator's opinion)**
Double blinded
**Blinding description**
Due to the apparent similarity of the drugs, the patient does not know the type of drug. The person who responsible for collection of patients' data and questionaries also does not know the type of drug.
**Placebo**
Not used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethics committee of Gastroenterology and Liver Diseases Research Institute, Shahid Beheshti Universi
**Street address**
Gastroenterology and Liver Diseases Research Institute, No 1, Ayatollah Taleghani Hospital, Shahid Arabi Ave., Yaman St., Shahid Chamran Highway, Tehran.
**City**
Tehran
**Province**
Tehran
**Postal code**
1985711151
**Approval date**
2021-07-19, 1400/04/28
**Ethics committee reference number**
IR.SBMU.RIGLD.REC.1400.015

## Health conditions studied

### 1

**Description of health condition studied**
Distal esophageal spasm
**ICD-10 code**
K22.4
**ICD-10 code description**
Dyskinesia of esophagus

## Primary outcomes

### 1

**Description**
Improvement of clinical manifestations (chest pain, dysphagia)
**Timepoint**
Before intervention and 2 months after intervention
**Method of measurement**
Questionnaire of patients symptoms, Questionnaire of quality of life, Eckardt score, Psychological questionnaire HADS and SF-36, esophageal manometry

## Secondary outcomes

### 1

**Description**
Improvement of esophageal manometric parameters
**Timepoint**
Before intervention and 2 months after intervention
**Method of measurement**

Esophageal manometry

## Intervention groups

### 1

**Description**

The first group will be treated with fluoxetine 10 mg daily and omeprazole 20 mg every 12 hours for 2 months. Completion of questionnaires and esophageal manometry will be done before and 2 months after the start of medication. Due to the apparent similarity of the drugs, the patient does not know the type of drug. The person who responsible for collection of patients' data and questionaries also does not know the type of drug.

**Category**

Treatment - Drugs

### 2

**Description**

The second group will be treated with diltiazem 30 mg daily and omeprazole 20 mg every 12 hours for 2 months. Completion of questionnaires and esophageal manometry will be done before and 2 months after the start of medication. Due to the apparent similarity of the drugs, the patient does not know the type of drug. The person who responsible for collection of patients' data and questionaries also does not know the type of drug.

**Category**

Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**

Taleghani hospital

**Full name of responsible person**

Ahmad Ghorbanpour Rasekh

**Street address**

Gastroenterology and Liver Diseases Research Institute, No 1, Ayatollah Taleghani Hospital, Shahid Arabi Ave., Yaman St., Shahid Chamran Highway, Tehran.

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## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Afshin Zarghi

**Street address**

Vice-chancellor in research affairs, No 1, Shahid Beheshti university of medical sciences, Shahid Arabi Ave., Yaman St., Shahid Chamran Highway, Tehran.

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**Phone**

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**Email**

zarghi@sbmu.ac.ir

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Ahmad Ghorbanpour Rasekh

**Position**

Subspecialized assistant

**Latest degree**

Specialist

**Other areas of specialty/work**

Internal Medicine

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## Person responsible for scientific inquiries

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## Person responsible for updating data

**Contact**

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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 further information.

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available