

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 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 questionnaires 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 AABBABBBBAA. 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 questionnaires 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

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 questionnaires 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 questionnaires 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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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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Full name of responsible person

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Position

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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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