

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The therapeutic effect of Midodrine in patients with refractory gastro esophageal reflux disease: a randomized double-blind clinical trial

#### Protocol summary

##### Summary

Gastro-oesophageal reflux disease (GERD) is known as esophageal mucosal injury or regurgitation of stomach contents. Acid reducing agents, particularly proton pump inhibitors (PPI), are effective in the management of GERD. However, about 20-30 % of affected cases do not respond to these agents. Therefore, other drugs that could affect the lower esophageal sphincter pressure or diminish its transient relaxations are possible choices. It is presumed that midodrine, an alpha agonist drug, may be effective in treating refractory patients according to above mentioned mechanisms. In this clinical trial, midodrine would be compared with placebo. Sixty patients between 18 to 65 ages who have already experienced at least one of the symptoms of heartburn or regurgitation despite one month consumption of High-dose PPIs will be included. Those with history of gastrointestinal surgery, concomitant diseases, use of certain medications, dysphagia and pregnancy are excluded from the study. Upper endoscopy with biopsy will be performed first. Then, randomly, cases are placed into 3 groups, one as placebo and two others taking two different dosages of midodrine for one month. As the primary outcome, patients are asked to score the intensity of their symptoms, based on a 0-10 visual scale, at the beginning of the study and then weekly up to 2 weeks after drug cessation. Previously validated Gastro esophageal reflux quality of life questionnaire will be filled out by the attendant manager biweekly. Finally, statistical analysis will be conducted.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201402274226N2**

Registration date: **2014-04-04, 1393/01/15**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2014-04-04, 1393/01/15

##### Registrant information

###### Name

Gholam Reza Sivandzadeh

###### Name of organization / entity

Shiraz University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 71 1647 4316

###### Email address

ghsivand@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Shiraz University of Medical Sciences

##### Expected recruitment start date

2014-04-21, 1393/02/01

##### Expected recruitment end date

2014-10-23, 1393/08/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The therapeutic effect of Midodrine in patients with refractory gastro esophageal reflux disease: a randomized double-blind clinical trial

##### Public title

Midodrine and refractory gastroesophageal disease

##### Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: age more than 18 and below 65; presence of at least one symptom compatible with GERD including epigastric or retrosternal burning sensation, regurgitation, or acid taste in the mouth; lack of response to the proper consumption of pantoprazole 40 mg twice daily for a minimum of one month. Exclusion criteria: dominant symptom of dysphagia; history of surgery of the upper GI system; concomitant GI diseases such as NET, malignancy, peptic ulcer disease; presence of other diseases like hypertension, cardiovascular diseases, history of urinary retention, hypersensitivity to midodrine, leg cramp or vascular insufficiency in the abdomen or legs, acute or chronic renal dysfunction with GFR < 50%, thyroid disease, diabetes mellitus, pheochromocytoma, liver cirrhosis, asthma or COPD; use of medications affecting lower esophageal sphincter such as theophylline, beta blockers, NSAIDs, steroids, bronchodilators; antihistamine taking; pregnancy and lactation; psychiatric disorders or use of antidepressive agents; current smoker; alcohol consumption; use of narcotics or illicit drugs; history of glaucoma.

## Age

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

## Gender

Both

## Phase

0

## Groups that have been masked

*No information*

## Sample size

Target sample size: **60**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Shiraz University of Medical Sciences

##### Street address

Namazi square, Zand street

##### City

Shiraz

##### Postal code

#### Approval date

2014-02-24, 1392/12/05

## Ethics committee reference number

CT-P-92-6683

## Health conditions studied

### 1

#### Description of health condition studied

gastroesophageal reflux disease

#### ICD-10 code

K21

#### ICD-10 code description

Gastro- oesophageal reflux disease

## Primary outcomes

### 1

#### Description

Symptom severity

#### Timepoint

Weekly

#### Method of measurement

Visual scale 0-10

### 2

#### Description

Quality of life

#### Timepoint

Every 2 weeks

#### Method of measurement

GERD quality of life standardized questionnaire

## Secondary outcomes

### 1

#### Description

Lower esophageal sphincter pressure

#### Timepoint

One month

#### Method of measurement

Mannometry

### 2

#### Description

Esophageal residual acid reflux

#### Timepoint

Monthly

#### Method of measurement

pH meter

## Intervention groups

### 1

#### Description

Midodrine, tablet 5 mg, 3 times per day for one month

#### Category

Treatment - Drugs

**2**

**Description**

Midodrine, tablet 2.5mg, 3 times per day for one month

**Category**

Treatment - Drugs

**3**

**Description**

Placebo, tablet, 3 times per day for one month

**Category**

Placebo

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Endoscopy ward, Namazi hospital

**Full name of responsible person**

Dr Gholam Reza Sivandzadeh, GI fellowship

**Street address**

Endoscopy ward, Namazi hospital

**City**

Shiraz

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Dr Sayyed Basir Hashemi

**Street address**

Namazi square- Zand street

**City**

Shiraz

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Shiraz University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

Gastroenterohepatology research center

**Full name of responsible person**

Gholam Reza Sivandzadeh

**Position**

GI fellowship

**Other areas of specialty/work**

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Gastroenterohepatology research center, Shiraz

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**Full name of responsible person**

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Full professor

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**Position**

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**Web page address**

## **Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

*empty*  
**Study Protocol**  
*empty*  
**Statistical Analysis Plan**  
*empty*  
**Informed Consent Form**  
*empty*  
**Clinical Study Report**  
*empty*  
**Analytic Code**  
*empty*  
**Data Dictionary**  
*empty*