Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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
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Iran (Islamic Republic of)
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+98 71 1647 4316
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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 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 Uiversity of Medical Scienes

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 qustionnaire

Secondary outcomes

1

Description

Lower esophageal sphincter pessure

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 timesper 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
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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
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact
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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