Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the efficacy of adding Domperidone to a proton pump inhibitor for the treatment of refractory gastroesophageal reflux disease

Protocol summary

Summary
Forty patients with refractory gastroesophageal disease (GERD) will be randomly divided into two groups to receive either Pantoprazole (40 mg BID) plus Domperidone (10mg TID) or Pantoprazole (40 mg BID) plus Placebo tablets (10mg TID) for one month. Related questionnaires including GERD questionnaire, Carlson Dennett and the Medical Outcomes Study Short Form-34 health survey (SF34) will be completed before and after treatment to assess treatment response.

General information

Acronym
IRCT registration information
IRCT registration number: **IRCT2017052134070N1**
Registration date: **2017-06-09, 1396/03/19**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**
Registration date
2017-06-09, 1396/03/19

Registrant information
Name
Zohreh Bari
Name of organization / entity
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Recruitment status
Recruitment complete
Funding source
Mazandaran University of Medical Sciences

Expected recruitment start date
2016-12-01, 1395/09/11
Expected recruitment end date
2017-08-01, 1396/05/10
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the efficacy of adding Domperidone to a proton pump inhibitor for the treatment of refractory gastroesophageal reflux disease

Public title
Evaluation of the efficacy of adding Domperidone for the treatment of refractory gastroesophageal reflux disease
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Patients with gastroesophageal reflux disease that do not partially or completely respond to treatment after taking twice daily proton pump inhibitor for one month Exclusion criteria: age below 18 or above 80 years; severe cardiopulmonary, renal or liver failure; pregnancy; breast feeding; history of gastro-esophageal surgery or malignancy
Age
From **18 years** old to **80 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **40**

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
Mazandaran University of Medical Sciences
Street address
Moallem Square
City
Sari
Postal code
Approval date
2016-08-09, 1395/05/19
Ethics committee reference number
IR.MAZUMS.REC.95-1939

Health conditions studied

1

Description of health condition studied
Gastro-oesophageal reflux disease
ICD-10 code
K21
ICD-10 code description
Gastro-oesophageal reflux disease

Primary outcomes

1

Description
Response to treatment
Timepoint
One month after starting therapy
Method of measurement
questionnnaires

Secondary outcomes

1

Description
Quality of life
Timepoint
One month after starting tratment
Method of measurement
Questionnaire

Intervention groups

1

Description
Intervention group: pantoprazole 40mg (BD) + Domperidone 10mg (TID)
Category
Treatment - Drugs

2

Description
Control group: pantoprazole 40mg (BD) + placebo tablet (TID)
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Dr. Torang Taghvaei
Street address
Amir Mazandarani street
City
Sari

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Dr. Ahmad Ali Enayati
Street address
Mazandaran University of Medical Sciences
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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
Mazandaran 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

Mazandaran University of Medical Sciences

Full name of responsible person

Dr. Tarang Taghvaei

Position

Associate professor, Gastroenterologist

Other areas of specialty/work

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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