

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

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

#### Protocol summary

Mazandaran University of Medical Sciences

#### 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.

#### 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

#### General information

#### Scientific title

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

#### Acronym

#### IRCT registration information

IRCT registration number: **IRCT2017052134070N1**

Registration date: **2017-06-09, 1396/03/19**

Registration timing: **registered\_while\_recruiting**

#### Public title

Evaluation of the efficacy of adding Domperidone for the treatment of refractory gastroesophageal reflux disease

Last update:

Update count: **0**

#### Registration date

2017-06-09, 1396/03/19

#### 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

#### Registrant information

#### Name

Zohreh Bari

#### Name of organization / entity

Mazandaran University of medical sciences

#### Country

Iran (Islamic Republic of)

#### Phone

+98 911 153 6575

#### Email address

zbari@mazums.ac.ir

#### 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**

#### Recruitment status

**Recruitment complete**

#### Funding source

**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**

questionnaires

**Secondary outcomes****1****Description**

Quality of life

**Timepoint**

One month after starting treatment

**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

**City**

Sari

**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*

48166 33131  
**Phone**  
+98 11 3336 1700  
**Fax**  
**Email**  
tarang\_taghvaei@yahoo.com  
**Web page address**

## 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**  
**Street address**  
Imam Khomeini Hospital, Amir Mazandarani street  
**City**  
Sari  
**Postal code**  
4816633131  
**Phone**  
+98 11 3336 1700  
**Fax**  
**Email**  
tarang\_taghvaei@yahoo.com  
**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Mazandaran University of Medical Sciences  
**Full name of responsible person**  
Dr. Totang Taghvaei  
**Position**  
Associate professor, Gastroenterologist  
**Other areas of specialty/work**  
**Street address**  
Imam Khomeini Hospital, Amir Mazandarani Street  
**City**  
Sari  
**Postal code**

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Mazandaran University of Medical Sciences  
**Full name of responsible person**  
Dr. Torang Taghvaei  
**Position**  
Associate professor, Gastroenterologist  
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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*