

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jun 2026

Comparison of The effect of Omeprazole,Pantoprazole,Esomeprazole and Lansoprazole on the Symptoms in Patients with Gastroesophageal Reflux Disease

Protocol summary

Study aim

The purpose of this study was to compare the effects of several proton pump inhibitors (including omeprazole, pantoprazole, esomeprazole and lansoprazole) on the symptoms of patients with Gastroesophageal Reflux Disease.

Design

This study is a randomized clinical trial (open-label), and the study was conducted for a period of 6 months. The sample size is determined using previous studies in Iran and statistical formulas . 30 persons in each intervention group are considered. Patients are randomly divided into four groups

Settings and conduct

The places for the study are Gastroenterology and Internal clinics of Isfahan province. Patients symptoms including HeartBurn and Acid Regurgitation will be measured in 0,2,4,8 week of treatment via questionnaire

Participants/Inclusion and exclusion criteria

Inclusion Criteria: patients with major symptoms of reflux disease ie HeartBurn and Acid Regurgitation that have two or more episodes of symptoms per week Exclusion Criteria :History of Cancer,Odinophagia,Dysphagia,Recent weight loss

Intervention groups

Group1 Omeprazole 40mg (OMP)-Manufactured by Abidi Pharma-Iran Group 2 Pantoprazole 40mg (PAN)-Manufactured by Abidi Pharma-Iran Group3 Esomeprazole 40mg (ESO)-Manufactured by Abidi Pharma-Iran Group4 Lansoprazole 30mg(LAN)-Manufactured by Abidi Pharma-Iran All drugs were administered daily for eight weeks

Main outcome variables

After 8 weeks of treatment, patients are evaluated for the chronic reflux symptoms and Satisfaction with the treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171007036616N1**

Registration date: **2018-10-01, 1397/07/09**

Registration timing: **retrospective**

Last update: **2018-10-01, 1397/07/09**

Update count: **0**

Registration date

2018-10-01, 1397/07/09

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3653 2021

Email address

qoghonus@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-21, 1396/11/01

Expected recruitment end date

2018-07-22, 1397/04/31

Actual recruitment start date

2018-01-21, 1396/11/01

Actual recruitment end date

2018-07-22, 1397/04/31

Trial completion date

2018-07-22, 1397/04/31

Scientific title

Comparison of The effect of Omeprazole,Pantoprazole,Esomeprazole and Lansoprazole on the Symptoms in Patients with Gastroesophageal Reflux Disease

Public title

Comparison of the Effect of Omeprazole,Pantoprazole,Esomeprazole and Lansoprazole on the Patients with Gastroesophageal Reflux Disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with Gastroesophageal Reflux Disease with frequent symptoms(2 or more symptoms per week)

Exclusion criteria:

Weight Loss History of cancer Odynophagia Dysphagia

Age

No age limit

Gender

Both

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: **120**

Actual sample size reached: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple: Patients were randomized in each of the four interventional groups by using Table of Random Digits. Patients who were excluded from the project for any reason were replaced by new patients.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan Medical University

Street address

Hezar Jarib

City

Isfahan

Province

Isfahan

Postal code

81774673461

Approval date

2017-05-30, 1396/03/09

Ethics committee reference number

IR.MUI.REC.1396.3.343

Health conditions studied

1

Description of health condition studied

Gastro-oesophageal Reflux Disease

ICD-10 code

K21

ICD-10 code description

Gastro-esophageal reflux disease

Primary outcomes

1

Description

Heart Burn

Timepoint

0 , 2 , 4 , 8 weeks

Method of measurement

questionnaire

2

Description

Acid Regurgitation

Timepoint

0 , 2 , 4 , 8 weeks

Method of measurement

questionnaire

Secondary outcomes

1

Description

Total Satisfaction

Timepoint

0,2,4,8 week

Method of measurement

Questionnaire

Intervention groups

1

Description

omeprazole 40mg daily(the pateint will consume two 20mg omeperazole capsules on fasting every morning for 8 weeks)

Category

Treatment - Drugs

2

Description

Pantoprazole 40mg daily(the pateint will consume one 40mg Pantoprazole capsule on fasting every morning for 8 weeks)

Category

Treatment - Drugs

3

Description

Esomeprazole 40mg daily(the pateint will consume one 40mg Esomeprazole capsule on fasting every morning for 8 weeks)

Category

Treatment - Drugs

4

Description

Lansoprazole 30mg daily(the pateint will consume one 30mg Lansoprazole capsule on fasting every morning for 8 weeks)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan Azzahra Hospital GastroIntestinal Clinic

Full name of responsible person

Nima Arezoomandi

Street address

Soffeh

City

Isfahan

Province

Isfahan

Postal code

8175887573

Phone

+98 31 3620 2020

Email

qogh nus@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Abidi Pharma

Full name of responsible person

Marzieh Jafari

Street address

Bokharest Ave.

City

Tehran

Province

Tehran

Postal code

1513815811

Phone

+98 21 8870 1600

Email

m.jafari@cobeldarou.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Abidi Pharma

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Industry

Person responsible for general inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Nima Arezoomandi

Position

Resident of Internal Medicine

Latest degree

Specialist

Other areas of specialty/work

Internal Medicine

Street address

Hakim Nezami

City

Isfahan

Province

Isfahan

Postal code

8175887573

Phone

+98 316532021

Email

qogh nus@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Nima Arezoomandi

Position

Resident of Internal Medicine

Latest degree
Medical doctor
Other areas of specialty/work
General Practitioner
Street address
Hakim Nezami
City
Isfahan
Province
Isfahan
Postal code
8175887573
Phone
+98 31 3653 2021
Email
qoghnus@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Nima Arezoomandi
Position
Resident of Internal Medicine
Latest degree
Medical doctor
Other areas of specialty/work
General Practitioner
Street address
Hakim Nezami
City
Isfahan
Province
Isfahan
Postal code

8175887573

Phone
+98 31 3653 2021

Email
qoghnus@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Questionnaire Informed consent form Outcomes

When the data will become available and for how long

6 month after publishing

To whom data/document is available

Any researcher

Under which criteria data/document could be used

Any Researcher

From where data/document is obtainable

Nima Arezoomandi, Email

What processes are involved for a request to access data/document

Email

Comments