Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 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, osoperazole 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 Opeprazole 40mg (OMP)-Manufactured by Abidi Pharma-Iran Gruop 2 Pantoperazole 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

qoghnus@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 Odinophagia 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
Isfehan
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
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Soffeh
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8175887573
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qoghnus@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
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Person responsible for updating data

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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 Reseacher
From where data/document is obtainable
Nima Arezoomandi,Email
What processes are involved for a request to access data/document
Email
Comments