Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the Effectiveness and Adverse Effects of Phorize (Vonoprazan) Versus Pantoprazole in Controlling Symptoms of Non-Erosive Reflux Disease (NERD) and Clinical Improvement of Erosive Esophagitis (EE)

Protocol summary

Study aim

To compare the effectivenes and adverse effects of vonoprazan with pantoprazole in controlling symptoms of Non-Erosive Reflux Disease (NERD) and achieving clinical improvement in Erosive Esophagitis (EE).

Design

The study is a randomized, double-blind, phase 3 clinical trial with 4 parallel intervention groups with a sample size of 730 patients. Sealed Envelope software was used for randomization.

Settings and conduct

Patients with NERD or EE will be enrolled in the study in selected medical centers in Tehran, Shiraz, Isfahan, Ahvaz, Mashhad, Tabriz, Rasht, and Sari, if eligible, and will be randomly assigned to one of the intervention groups using a randomized block design. This study will be conducted in a double-blind manner.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Diagnosis of NERD or EE confirmed by an experienced and active endoscopist within the past 6 months, Exclusion Criteria: History of failed treatment with proton pump inhibitors ,fundoplication, gastrectomy, Barrett’s esophagus, dysplasia, Peptic ulcer disease, Gastrointestinal bleeding

Intervention groups

In the EE arm, the first intervention group will receive vonoprazan 20 milligrams (mg) once daily for 8 weeks and then vonoprazan 10 mg once daily for 16 weeks. The second intervention group will receive pantoprazole 40 mg once daily for 8 weeks and then pantoprazole 20 mg once daily for 16 weeks. In the NERD arm, the third intervention group will receive vonoprazan 10 mg once daily for 8 weeks. The fourth intervention group will receive pantoprazole 20 mg once daily for 8 weeks. Vonoprazan: Abidi (Phorize), Pantoprazole: Tehran Shimi (Pentomid)

Main outcome variables

Heartburn-free time (daytime and night time). Number of heartburn-free days during the study period. Percentage of participants without heartburn at the end of the study.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251101067844N1**
Registration date: **2026-01-13, 1404/10/23**
Registration timing: **prospective**

Last update: **2026-01-13, 1404/10/23**
Update count: **0**

Registration date

2026-01-13, 1404/10/23

Registrant information

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-01-21, 1404/11/01

Expected recruitment end date

2027-08-06, 1406/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effectiveness and Adverse Effects of Phorize (Vonoprazan) Versus Pantoprazole in Controlling Symptoms of Non-Erosive Reflux Disease (NERD) and Clinical Improvement of Erosive Esophagitis (EE)

Public title

A Comparative Study of Vonoprazan and Pantoprazole in the Treatment of NERD and Erosive Esophagitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

diagnosis of Non-Erosive Reflux Disease (NERD) or Erosive Esophagitis (EE) based on endoscopy, with any severity level requiring pharmacologic treatment Patients diagnosed with NERD or EE by an experienced and active endoscopist within the past 6 months.

Exclusion criteria:

Refractory erosive esophagitis or previous failure to respond to treatment with proton pump inhibitors History of fundoplication surgery or gastrectomy. History of Barrett’s esophagus or esophageal dysplasia. Presence of peptic ulcer disease. History of gastrointestinal bleeding or endoscopic stigmata of recent bleeding Severe dyspeptic symptoms Advanced Chronic Kidney Disease Moderate to severe hepatic impairment Pregnancy, intention to become pregnant, or breastfeeding. Concomitant Use of Rilpivirine, Digoxin, Methotrexate, Diuretics

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **730**

Randomization (investigator's opinion)

Randomized

Randomization description

Sealed Envelope Ltd.2024 software was used. In the erosive esophagitis arm, a total of 438 patients were numbered. Randomization was performed in blocks of 4 in a 1:1 ratio by assigning 3-letter codes consisting of numbers and Latin letters to the patient numbers. Accordingly, half of the patients will receive venoprazan and the other half will receive pantoprazole. In the non-erosive reflux disease arm, a total of 292 patients were numbered. In blocks of 4 in a 1:1 ratio, randomization was performed by assigning 3-letter codes consisting of numbers and Latin letters to the patient numbers. Accordingly, half of the patients will receive venoprazan and the other half will receive pantoprazole. The list of codes assigned to each patient in both study arms is kept in separate Excel files only accessible to the epidemiologist and study executive director and will not be made available to the treatment centers or patients.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients will be informed that they will be given one of two gastroesophageal reflux disease treatments, pantoprazole or vonoprazan, and that the type of medication assigned will not be known until the end of the study. In both study arms, medications were packaged in unlabeled, sealed, single-color bottles. The required medication bottles were placed in identical paper envelopes. The patient number and assigned randomization code were affixed to the bottle and the paper envelope. According to the instructions sent to the patient admission centers, in both study arms, patient admission will be done by number and in order. Therefore, patients and admission centers are blinded to the assigned medication.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committe of Iran University of Medical Sciences

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Iran University of Medical Sciences, next to Milad Tower, Hemmat Highway,

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Approval date

2025-11-15, 1404/08/24

Ethics committee reference number

IR.IUMS.REC.1404.792

Health conditions studied

1

Description of health condition studied
Gastro-esophageal Reflux Disease
ICD-10 code
K21
ICD-10 code description
Gastro-esophageal reflux disease

Primary outcomes

1

Description
Total heartburn-free time (Daytime)
Timepoint
The time of intervention is considered as week 0. Non-erosive reflux arm: right before starting the treatment (week 0), week 4 and week 8, Erosive esophagitis arm: right before starting the treatment (week 0), week 4, week 8, week 12, week 16, week 20, week 24
Method of measurement
Single designed form (By study researchers) for recording daytime and nighttime symptoms and the use of rescue medications for symptom control

2

Description
Total heartburn-free time (night time)
Timepoint
The time of intervention is considered as week 0. Non-erosive reflux arm: right before starting treatment (week 0), week 4 and week 8, Erosive esophagitis arm: right before starting treatment (week 0), week 4, week 8, week 12, week 16, week 20, week 24
Method of measurement
Single designed form (By study researchers) for recording daytime and nighttime symptoms and the use of rescue medications for symptom control

3

Description
Total Heartburn free days
Timepoint
The time of intervention is considered as week 0. Non-erosive reflux arm: right before starting treatment (week 0), week 4 and week 8, Erosive esophagitis arm: right before starting treatment (week 0), week 4, week 8, week 12, week 16, week 20, week 24
Method of measurement
Single designed form (By study researchers) for recording daytime and nighttime symptoms and the use of rescue medications for symptom control

4

Description
Percentage of Heartburn-free individuals at the end of the study
Timepoint
The time of intervention is considered as week 0. Non-erosive reflux arm: right before starting treatment (week 0), week 4 and week 8, Erosive esophagitis arm: right before starting treatment (week 0), week 4, week 8, week 12, week 16, week 20, week 24
Method of measurement
Single designed form (By study researchers) for recording daytime and nighttime symptoms and the use of rescue medications for symptom control

Secondary outcomes

1

Description
the GERD-Q (Gastroesophageal Reflux Disease Questionnaire) Score
Timepoint
The time of intervention is considered as week 0. Non-erosive reflux arm: right before starting treatment (week 0), week 4 and week 8, Erosive esophagitis arm: right before starting treatment (week 0), week 4, week 8, week 12, week 16, week 20, week 24
Method of measurement
the GERD-Q (Gastroesophageal Reflux Disease Questionnaire)

2

Description
Score of GSAS : GERD Symptom Assessment Scale
Timepoint
The time of intervention is considered as week 0. Non-erosive reflux arm: right before starting treatment (week 0), week 4 and week 8, Erosive esophagitis arm: right before starting treatment (week 0), week 4, week 8, week 12, week 16, week 20, week 24
Method of measurement
GSAS : GERD Symptom Assessment Scale Queestionnaire

3

Description
Adverse effects
Timepoint
The time of intervention is considered as week 0. Non-erosive reflux arm: right before starting treatment (week 0), week 4 and week 8, Erosive esophagitis arm: right before starting treatment (week 0), week 4, week 8, week 12, week 16, week 20, week 24
Method of measurement
pre-designed forms of adverse effects

Intervention groups

1

Description
Intervention group one: Erosive Esophagitis (EE), Vonoprazan Arm, Participants will receive vonoprazan (phorize, Abidi) 20 milligrams tablets once daily for 8 weeks as initial treatment, followed by vonoprazan 10

miligrams tablets once daily for 16 weeks as maintenance treatment.

Category
Treatment - Drugs

2

Description
Intervention group two: Erosive Esophagitis (EE), Pantoprazole Arm, Participants will receive pantoprazole (Pentomid, Tehran Shimi) 40 milligrams once daily, taken before breakfast, followed by Pentomid 20 milligrams before breakfast for 16 weeks.

Category
Treatment - Drugs

3

Description
Intervention Group three: Non-Erosive Reflux Disease (NERD), Vonoprazan Arm, Participants will receive vonoprazan (phorize, Abidi) 10 milligrams tablets once daily for 8 weeks.

Category
Treatment - Drugs

4

Description
Intervention Group four: Non-Erosive Reflux Disease (NERD), Pantoprazole Arm, Participants will receive pantoprazole (Pentomid, Tehran Shimi) 20 milligram tablets once daily, taken before breakfast for 8 weeks.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
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Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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
Abidi Pharmaceutical company

Proportion provided by this source
99

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

2

Sponsor

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
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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
Iran University of Medical Sciences

Proportion provided by this source
1

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

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Professor

Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available