Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the Efficacy and Safety of Vonoprazan-Based Triple Therapy versus Esomeprazole-Based Triple Therapy for Helicobacter pylori Eradication

Protocol summary

Study aim

Comparison of the Efficacy and Safety of Vonoprazan-Based Triple Therapy versus Esomeprazole-Based Triple Therapy for Helicobacter pylori Eradication

Design

This study is a randomized clinical trial conducted in the internal medicine ward of Imam Khomeini Hospital in Ahvaz on patients infected with Helicobacter pylori. Patients aged 18 to 65 years with a positive H. pylori test and no prior treatment history will be enrolled. Exclusion criteria include recent use of antibiotics or acid-suppressing drugs, active complicated peptic ulcer, history of gastric surgery, drug allergies, severe physical or psychiatric illnesses, pregnancy or lactation, and history of alcohol or substance abuse. Patients will be randomly assigned to two treatment groups using permuted block randomization (block sizes of 4, 6, and 8). Allocation will be concealed using opaque, sealed, and sequentially numbered envelopes to ensure that the assigned group is unknown before enrollment (concealment allocation). Participants will be blinded to the type of treatment they receive. After group assignment, patients will receive the corresponding therapy for H. pylori eradication.

Settings and conduct

The present study is a randomized clinical trial conducted in the internal medicine ward of Imam Khomeini Hospital in Ahvaz on patients infected with Helicobacter pylori.

Participants/Inclusion and exclusion criteria

Their test results indicate a positive Helicobacter pylori infection.

Intervention groups

Triple Therapy Group A: Vonoprazan 20 mg twice daily, Amoxicillin 1 g twice daily, Clarithromycin 500 mg twice daily for 14 days. Triple Therapy Group B: Esomeprazole 20 mg twice daily, Amoxicillin 1 g twice daily, Clarithromycin 500 mg twice daily for 14 days.

Main outcome variables

Helicobacter pylori eradication rate: Safety and adverse effects of treatment:

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250919067288N1**
Registration date: **2025-12-26, 1404/10/05**
Registration timing: **registered_while_recruiting**

Last update: **2025-12-26, 1404/10/05**
Update count: **0**

Registration date

2025-12-26, 1404/10/05

Registrant information

Name

Seyed Saeed Seyedian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3333 8556

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-10-23, 1404/08/01

Expected recruitment end date

2026-02-20, 1404/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Efficacy and Safety of Vonoprazan-Based Triple Therapy versus Esomeprazole-Based Triple Therapy for Helicobacter pylori Eradication

Public title

Comparison of Efficacy and Safety of Two Triple Therapy Regimens for Helicobacter pylori Eradication

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Their test results indicate a positive Helicobacter pylori infection.

Exclusion criteria:

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant

Sample size

Target sample size: **184**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, interventions are assigned to participants according to a pre-generated randomization list. For allocation concealment, we use the concealment allocation method, which ensures that the assigned group of a participant is not known before the assignment. Opaque, sealed, and sequentially numbered envelopes are used, where each randomization sequence is recorded on a card and placed inside the envelopes in order. To maintain the randomization sequence, the external surface of the envelopes is numbered correspondingly. The envelopes are then sealed and placed sequentially in a box. At the time of participant enrollment, based on the order of eligible participants, an envelope is opened, revealing the treatment group assigned to that participant. After patients are allocated to the two treatment groups following the diagnosis of Helicobacter pylori infection and confirmation of eligibility, participants remain blinded to the type of treatment they receive.

Blinding (investigator's opinion)

Single blinded

Blinding description

This study uses a single-blind design, in which participants are unaware of their assigned treatment group. Allocation to treatment groups is concealed using opaque, sealed, and sequentially numbered envelopes, each containing a pre-generated randomization assignment. Envelopes are opened sequentially upon participant enrollment, revealing the allocated intervention. In addition to participants, clinical caregivers, outcome assessors, and data analysts are blinded to each participant's treatment allocation to minimize bias.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee

Street address

Faculty of Medicine, Ahvaz Jundishapur University of Medical Sciences, Golestan Street, Ahvaz, Iran

City

Ahvaz

Province

Khouzestan

Postal code

15794-61357

Approval date

2025-09-13, 1404/06/22

Ethics committee reference number

IR.AJUMS.REC.1404.304

Health conditions studied

1

Description of health condition studied

Helicobacter pylori

ICD-10 code

K90-K93

ICD-10 code description

XI Diseases of the digestive system

Primary outcomes

1

Description

The primary outcome variable of this study is eradication of Helicobacter pylori infection after a 14-day treatment course. Eradication will be assessed using the stool Helicobacter pylori antigen test at the end of the treatment period. This variable reflects the efficacy of the interventions (triple therapy based on vonoprazan or esomeprazole).

Timepoint

The primary outcome variable, H. pylori eradication, will

be measured at the end of the 14-day treatment period. Additionally, drug-related adverse effects will be recorded daily throughout the treatment period to assess patient safety and tolerability of the therapy.

Method of measurement

The primary outcome variable, H. pylori eradication, will be measured using the H. pylori stool antigen test (HpSAT) after the 14-day treatment period. Additionally, drug-related adverse effects will be recorded daily through questionnaires and clinical observation to assess treatment safety and tolerability.

Secondary outcomes

1

Description

Drug side effects: including headache, dizziness, weakness, confusion, dry mouth, nausea, bloating, and abdominal pain.Patient adherence to treatment: the extent to which patients follow the 14-day prescribed treatment regimen.Changes in clinical symptoms: including reduction or improvement of gastrointestinal symptoms such as abdominal pain, indigestion, and bloating.Treatment discontinuation rate: the number of patients who discontinue the treatment for any reason.

Timepoint

Baseline (before treatment): Recording initial Helicobacter pylori test results and clinical symptoms of the patient.During treatment (Day 7): Monitoring drug side effects and patient adherence to therapy.End of treatment (Day 14): Performing Helicobacter pylori stool antigen test to assess treatment efficacy and recording side effects.Post-treatment follow-up (optional, depending on study design): Evaluating the persistence of eradication and clinical symptoms at a specified time after treatment completion.

Method of measurement

Primary outcome (Helicobacter pylori eradication): Assessed using the Helicobacter pylori stool antigen (HpSA) test after the 14-day treatment period.Secondary outcomes (drug side effects): Recorded through clinical interviews and patient-reported questionnaires during and at the end of the treatment period. Side effects include headache, dizziness, weakness, confusion, dry mouth, nausea, bloating, and abdominal pain.Treatment adherence: Evaluated through interviews and review of patient-reported medication intake throughout the treatment period.

Intervention groups

1

Description

In this study, after confirming Helicobacter pylori infection and meeting the inclusion criteria, patients are randomly assigned to two treatment groups:Triple Therapy Group A:Vonoprazan 20 mg, twice dailyAmoxicillin 1 g, twice dailyClarithromycin 500 mg, twice dailyTreatment duration: 14 daysTriple Therapy Group B:Esomeprazole 20 mg, twice dailyAmoxicillin 1 g, twice dailyClarithromycin 500 mg, twice dailyTreatment duration: 14 daysAt the end of the treatment period, all patients will undergo a stool Helicobacter pylori antigen test to assess treatment efficacy.Monitoring of adverse effects: During the treatment period, drug-related side effects including headache, dizziness, weakness, confusion, dry mouth, nausea, bloating, and abdominal pain will be recorded through clinical interviews and patient self-report questionnaires.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Khomeini Hospital

Full name of responsible person
mehrasa heydari

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Ahvaz, Golestan Street, Ahvaz Jundishapur University of Medical Sciences, Faculty of Medicine

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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
Ahvaz University of Medical Sciences
Proportion provided by this source
100
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
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Seyed Saeed Seyedian
Position
Associate professo
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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
In this study, individual participant data (IPD) will be available after completion of the research and following proper de-identification to ensure confidentiality. Data related to the primary outcome (eradication of Helicobacter pylori) and secondary outcomes (adverse drug reactions and other related outcomes) will be shared in the form of anonymized datasets. Other study documents, including the study protocol, questionnaires, and case report forms (CRFs), will also be available upon reasonable request by qualified researchers. Data sharing will only take place after submission of a formal

written request and subsequent approval by the Ethics Committee and the research team.

When the data will become available and for how long

The study data and documents will be available to eligible researchers starting 6 months after the publication of the final results in peer-reviewed journals, for a period of 3 years. After this period, access will only be granted upon approval by the ethics committee and the research team.

To whom data/document is available

Individuals who are allowed to access the data/documents include academic researchers, postgraduate students, and other qualified investigators who submit a formal request and obtain approval from the ethics committee and the research team.

Under which criteria data/document could be used

The data/documents will be available exclusively for research and scientific purposes, and their use will be permitted only upon formal request, approval from the ethics committee, and strict adherence to participant confidentiality.

From where data/document is obtainable

To obtain the data/documents, interested researchers may contact the principal investigator at the Department of Internal Medicine, Imam Khomeini Hospital, or Ahvaz Jundishapur University of Medical Sciences.

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

Requests for access to the data/documents must be submitted in writing to the principal investigator. Upon receipt, the research team and ethics committee will review the request. If approved, the data will be provided to the requesting researcher after removal of any identifying information and in accordance with confidentiality regulations.

Comments