# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

09 Nov 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)

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sssydyan@yahoo.com


**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

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

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seyedian-ss@ajums.ac.ir

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**
Ahvaz 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**
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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Subspecialist
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Internal Medicine
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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**