Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of Vonoprazan-Amoxicillin versus Lansoprazole-Amoxicillin Dual Therapy for Treatment-Resistant Helicobacter pylori Infection: A Randomized Clinical Trial

Protocol summary

Study aim
To compare the efficacy of Vonoprazan-Amoxicillin dual therapy with Lansoprazole-Amoxicillin dual therapy in eradicating treatment-resistant Helicobacter pylori infection.

Design
A randomized, double-blind, parallel-group clinical trial, Phase 3, enrolling 160 patients; Randomization is performed using block method.

Settings and conduct
The study is conducted at selected clinical centers. Double-blind procedure is implemented through identical-looking capsules and uniform packaging of medications; Allocation is concealed using sequentially numbered and sealed envelopes; Participants; care providers; and outcome assessors are blinded.

Participants/Inclusion and exclusion criteria
160 participants aged 18 to 70 years with treatment-resistant Helicobacter pylori infection; Inclusion criteria: Age 18 to 70 years; confirmed infection; failure of at least one prior regimen; Exclusion criteria: Pregnancy; lactation; known drug hypersensitivity; severe hepatic or renal disease.

Intervention groups
Vonoprazan group: Vonoprazan (20 mg twice daily) plus Amoxicillin (1 g twice daily) for 14 days; Lansoprazole group (comparison): Lansoprazole (30 mg twice daily) plus Amoxicillin (1 g twice daily) for 14 days.

Main outcome variables
Helicobacter pylori eradication rate (confirmed by stool antigen test or urea breath test 4 to 12 weeks after treatment completion).

General information

Reason for update
Acronym

IRCT registration information
IRCT registration number: **IRCT20251010067573N1**
Registration date: **2025-11-10, 1404/08/19**
Registration timing: **prospective**

Last update: **2025-11-10, 1404/08/19**
Update count: **0**

Registration date
2025-11-10, 1404/08/19

Registrant information
Name
Mohammadamin Taheri
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Recruitment status
recruiting
Funding source

Expected recruitment start date
2025-11-16, 1404/08/25
Expected recruitment end date
2026-06-21, 1405/03/31
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of Vonoprazan-Amoxicillin versus Lansoprazole-Amoxicillin Dual Therapy for Treatment-

Resistant Helicobacter pylori Infection: A Randomized Clinical Trial

Public title
Comparison of Vonoprazan-Amoxicillin versus Lansoprazole-Amoxicillin Dual Therapy for Treatment-Resistant H. pylori

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age 18-70 years Confirmed Helicobacter pylori infection by stool antigen test and/or rapid urease test and/or gastric biopsy Failure to respond to at least one previous standard first-line H. pylori eradication regimen (treatment-resistant H. pylori) Written informed consent to participate in the study

Exclusion criteria:
Known allergy to vonoprazan, lansoprazole, amoxicillin, or other proton pump inhibitors Pregnancy or lactation History of gastric surgery Severe hepatic or renal disease Use of antibiotics or proton pump inhibitors in the last 4 weeks Gastrointestinal malignancy or inflammatory bowel disease Unwillingness to continue cooperation during the study

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **160**

Randomization (investigator's opinion)
Randomized

Randomization description
Participant allocation to the two treatment arms (Vonoprazan-Amoxicillin and Lansoprazole-Amoxicillin) will be performed using Block Randomization with variable block sizes. This method is used to ensure an approximately equal distribution of participants between the two groups throughout the recruitment period, thereby maintaining balance.The randomization unit is at the Individual level.The random sequence will be generated by an individual independent of the study's executive team, utilizing a statistical software package (such as R or Stata). This output will establish the allocation sequence (Group A or Group B).Allocation concealment will be ensured through the use of sequentially numbered, opaque, and sealed envelopes. These envelopes, containing the group assignment code (A or B), will be prepared according to the random sequence and held by an independent party (e.g., the study pharmacist). After the final confirmation of eligibility criteria by the physician, the next available numbered envelope will be assigned to the participant and opened to reveal the treatment group. This procedure ensures that neither the treating physician nor the participant can foresee the next assignment prior to enrollment.

Blinding (investigator's opinion)
Double blinded

Blinding description
The study will employ a double-blind design, ensuring that both the participants (patients) and the clinical team responsible for treatment and outcome assessment (physicians and assessors) are unaware of the treatment allocation. To implement this, the comparative drugs (Vonoprazan and Lansoprazole) will be prepared and packaged by the study pharmacist in capsules or containers that are identical in appearance, color, and size. These medications will be distributed using a secure, pre-assigned coding system (Allocation Concealment). The code will be held by an independent party and remain unbroken until the final data analysis. The primary outcome assessment (H. pylori eradication status via the Stool Antigen Test) will also be performed by a blinded investigator.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee in Research, Afzalipour Educational and Therapeutic Center – Kerman University of M

Street address
Imam Khomeini Highway, next to Shahid Bahonar University, Afzalipour Educational and Therapeutic Center

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Kerman

Province
Kerman

Postal code
7616913355

Approval date
2025-11-08, 1404/08/17

Ethics committee reference number
IR.KMU.AH.REC.1404.170

Health conditions studied

1

Description of health condition studied
Helicobacter pylori infection

ICD-10 code
B96.81

ICD-10 code description
Helicobacter pylori [H. pylori] as the cause of diseases classified elsewhere

Primary outcomes

1

Description
The primary outcome variable of the study is the frequency of Helicobacter pylori eradication. Successful eradication is defined as a negative Stool Antigen Test result during the post-treatment follow-up.
Timepoint
The primary outcome variable (Helicobacter pylori eradication) will be measured four weeks after completion of the treatment period.
Method of measurement
The primary outcome variable will be measured using the Stool Antigen Test.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: This group will receive the dual therapy regimen consisting of Vonoprazan and Amoxicillin. The Vonoprazan dose is 20 milligrams, twice daily , and the Amoxicillin dose is 1 gram, twice daily. The treatment duration for this group is 14 days, and the administration method is oral.
Category
Treatment - Drugs

2

Description
Control group: This group will receive the dual therapy regimen consisting of Lansoprazole and Amoxicillin. The Lansoprazole dose is 30 milligrams, twice daily , and the Amoxicillin dose is 1 gram, twice daily. The treatment duration for this group is also 14 days, and the administration method is oral.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Afzalipour Hospital
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
Kerman 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
Kerman University of Medical Sciences
Full name of responsible person

Masoumeh Rabbani

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Internal Medicine

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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