

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

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		procedure ensures that neither the treating physician nor the participant can foresee the next assignment prior to enrollment.	
Public title	Comparison of Vonoprazan-Amoxicillin versus Lansoprazole-Amoxicillin Dual Therapy for Treatment-Resistant H. pylori	Blinding (investigator's opinion)	Double blinded
Purpose	Treatment	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.
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	Placebo	Not used
Age	From 18 years old to 70 years old	Assignment	Parallel
Gender	Both	Other design features	
Phase	3	Secondary Ids	empty
Groups that have been masked	- Participant - Investigator - Outcome assessor	Ethics committees	
Sample size	Target sample size: 160	1	
Randomization (investigator's opinion)	Randomized	Ethics committee	
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	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
		City	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

Rostam Yazdani

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Imam Khomeini Highway, next to Shahid Bahonar

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

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Somayeh (Tahmasb Abad) Crossroad, beginning of Avicenna Street, Deputy of Research and Technology

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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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Position

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Latest degree

Medical doctor

Other areas of specialty/work

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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