

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Comparison of the efficacy of Vonoprazan with omeprazole in the quadruple therapy of Helicobacter pylori infection

Protocol summary

Study aim

Comparison of the efficacy of vonoprazan versus omeprazole in Helicobacter pylori quadruple therapy

Design

This double-blind clinical trial utilizes block randomization to allocate 150 participants equally into an intervention group (Group A, n:75) and a control group (Group B, n:75).

Settings and conduct

A double-blind, case-control clinical trial conducts at two hospitals in Isfahan. 150 consecutive patients aged 18 to 50, presenting with symptoms of dyspepsia and testing positive for *Helicobacter pylori* via endoscopic biopsy, are enrolled in the study.

Participants/Inclusion and exclusion criteria

Inclusion is defined as being between the ages of 18 and 50 and having a diagnosis confirmed by a positive endoscopic biopsy. Exclusion criteria for the study are as follows: 1) Antibiotic treatment within the past 3 months, 2) Use of H2 receptor antagonists, bismuth, or PPIs within 2 weeks prior to the study start, 3) A history of Helicobacter pylori eradication therapy within the past 5 years, 4) Use of NSAIDs and corticosteroids, 5) Severe comorbidities such as malignant disease, or a history of upper gastrointestinal issues such as diaphragmatic hernia, Barrett's esophagus, and achalasia, 6) Pregnancy or lactation, 7) A history of using immunosuppressive drugs, 8) Patients with inherited immunodeficiency, 9) Patients with poorly controlled diabetes, 10) Individuals unable to adhere to the treatment protocol.

Intervention groups

The intervention group received a 14-day ciprofloxacin-based quadruple therapy regimen: Ciprofloxacin (500 mg b.i.d.), Amoxicillin (500 mg b.i.d.), Vonoprazan (10 mg b.i.d.), and Bismuth (120 mg q.i.d.).

Main outcome variables

Improvement of disease symptoms- Improvement of side effects from the quadruple therapy drugs- Negative H. pylori stool antigen test

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250824066979N1**

Registration date: **2026-07-07, 1405/04/16**

Registration timing: **prospective**

Last update: **2026-07-07, 1405/04/16**

Update count: **0**

Registration date

2026-07-07, 1405/04/16

Registrant information

Name

Mahsa Tavangaran

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 4523 0036

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mahsatavangaran@gmail.com

Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-07-23, 1405/05/01

Expected recruitment end date

2026-09-23, 1405/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy of Vonoprazan with omeprazole in the quadruple therapy of Helicobacter pylori infection		drug coded with a unique serial number, without disclosure of the drug type. The manuscript authors will remain blinded to the identity of the groups until the completion of recruitment, database lock, and the initial analysis	
Public title	Comparison of the efficacy of Vonoprazan with omeprazole in the quadruple therapy of Helicobacter pylori infection	Placebo	Not used
Purpose	Treatment	Assignment	Parallel
Inclusion/Exclusion criteria	Inclusion criteria: confirmed pathology in endoscopic species or stool exam age between 18 to 50 lack of Helicobacter pylori infection treatment in the past 3 months negative drug allergy Exclusion criteria: poor compliant patients anti-biotic therapy during the last 3 months pregnancy or breast-feeding	Other design features	
Age	From 18 years old to 50 years old	Secondary Ids	empty
Gender	Both	Ethics committees	<u>1</u>
Phase	3	Ethics committee	
Groups that have been masked	- Participant - Investigator	Name of ethics committee	Ethics committee of Islamic Azad University-Najaf Abad Branch
Sample size	Target sample size: 150	Street address	Daneshgah Street
Randomization (investigator's opinion)	Randomized	City	Isfahan
Randomization description	The randomization technique employed in this study is the block method. In this process, patients are first divided into groups of four. Next, blocks representing four different arrangements of groups A and B are defined—specifically AABB, ABAB, ABBA, BBAA, BABA, and BAAB—resulting in a total of six block types. Subsequently, Microsoft Excel is used to generate random numbers corresponding to the number of groups; the groups are then sorted based on these numbers (in ascending order) and assigned to the designated blocks. Finally, the patients previously assigned to each group are allocated to one of the intervention groups (A or B) according to the sequence established within their respective blocks. Finally, using the numbered-envelope technique, groups A and B are assigned to either the intervention or the control group. In this way, patients are randomly distributed in equal numbers between the two study groups; Group A is designated as the intervention group, and Group B as the control group.	Province	Isfahan
Blinding (investigator's opinion)	Double blinded	Postal code	8316836489
Blinding description	In this study, a double-blind design will be used. Both the participants and the principal investigators will be completely blinded to the assignment of the study groups (study treatment or routine treatment). This will be achieved by preparing the study drug and the routine	Approval date	2025-06-05, 1404/03/15
		Ethics committee reference number	IR.IAU.NAJAFABAD.REC.1404.082
		Health conditions studied	<u>1</u>
		Description of health condition studied	بیماری هلیکوباکتری پیلوری
		ICD-10 code	B96.81
		ICD-10 code description	Helicobacter pylori [H. pylori] as the cause of diseases classified elsewhere
		Primary outcomes	<u>1</u>
		Description	Remission
		Timepoint	one month later
		Method of measurement	stool exam
		Secondary outcomes	

1

Description

Eradication

Timepoint

One month later

Method of measurement

stool exam

Intervention groups

1

Description

Intervention group: Patients presenting with symptoms of dyspepsia or epigastric pain and a positive endoscopic biopsy undergo a 14-day treatment regimen consisting of bismuth (300 mg four times daily), vonoprazan (20 mg twice daily), amoxicillin (1000 mg twice daily), and clarithromycin (500 mg twice daily); they are subsequently evaluated for eradication using a stool antigen test one month after the completion of treatment.

Category

Treatment - Drugs

2

Description

Control group: Patients presenting with symptoms of dyspepsia or epigastric pain and a positive endoscopic biopsy undergo a 14-day treatment regimen consisting of bismuth (300 mg four times daily), omeprazole (20 mg twice daily), amoxicillin (1000 mg twice daily), and clarithromycin (500 mg twice daily); they are subsequently evaluated for eradication using a stool antigen test one month after the completion of treatment.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

office

Full name of responsible person

Dr Hamid Mohajer

Street address

shariati street

City

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Province

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00000000

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+98 936 041 1998

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mahsatavangaran@gmail.com

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?

No

Title of funding source

IAUN

Proportion provided by this source

10

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

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Mahsa Tavangaran

Position

Student

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No further information available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

study protocol clinical study report

When the data will become available and for how long

access begins one year after publication of results

To whom data/document is available

all qualified individuals

Under which criteria data/document could be used

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From where data/document is obtainable

Islamic Azad university- Najafabad Branch

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

Email

Comments