Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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Iran (Islamic Republic of)

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+98 31 4523 0036

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Recruitment status
Recruitment complete

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

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

Purpose
Treatment

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

Age
From **18 years** old to **50 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **150**

Randomization (investigator's opinion)
Randomized

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.

Blinding (investigator's opinion)
Double blinded

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 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

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Islamic Azad University-Najaf Abad Branch

Street address
Daneshgah Street

City
Isfahan

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Isfehan

Postal code
8316836489

Approval date
2025-06-05, 1404/03/15

Ethics committee reference number
IR.IAU.NAJAFABAD.REC.1404.082

Health conditions studied

1

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

1

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
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Sponsors / Funding sources

1

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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
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Mahsa Tavangaran
Position
Student
Latest degree
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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