Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of the effectiveness of three treatment regimens including a two-drug regimen of amoxicillin and venoprazone, a three-drug regimen of amoxicillin, venoprazone, and levofloxacin, and a four-drug regimen of esomeprazole, amoxicillin, metronidazole, and bismuth in eradicating Helicobacter pylori.

Protocol summary

Study aim

Comparison of the effectiveness of three treatment regimens, including the two-drug regimen of amoxicillin-venoprazan, the three-drug regimen of amoxicillin-venoprazan-levofloxacin, and the four-drug regimen of omeprazole, amoxicillin, metronidazole, and bismuth, in eradicating Helicobacter pylori.

Design

Clinical trial, with 3 parallel groups, randomized, single-blind, phase 3 on 150 patients. Randomization via the rand function of Excel software

Settings and conduct

This clinical trial is being conducted at the Gastroenterology Clinic of Taleghani Hospital. Patients with Helicobacter pylori infection will be randomly assigned to three different treatment groups in a 1:1:1 ratio. The primary outcome measure, the stool antigen test result, will be assessed 6 to 8 weeks after the end of treatment. This study is a single-blind design, with only the outcome assessor blinded to the type of intervention participants received.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Definite diagnosis of Helicobacter pylori infection, willingness to participate in the study, and completion of the treatment course. Exclusion criteria: History of previous treatment for Helicobacter pylori eradication, use of antibiotics or proton pump inhibitors within the past 4 weeks.

Intervention groups

The first group received a two-drug regimen of amoxicillin 1 g twice daily and venoprazan 20 mg twice daily for 10 days. The second group received a three-drug regimen of amoxicillin 1 g twice daily, venoprazan 20 mg twice daily, and levofloxacin 500 mg once daily. The third group received the four-drug regimen of esomeprazole 40 mg twice daily, amoxicillin 1 g twice daily, metronidazole 500 mg twice daily, and bismuth 240 mg twice daily. The duration of drug administration was 14 days.

Main outcome variables

Helicobacter pylori eradication, treatment safety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220417054557N3**
Registration date: **2025-11-26, 1404/09/05**
Registration timing: **registered_while_recruiting**

Last update: **2025-11-26, 1404/09/05**
Update count: **0**

Registration date

2025-11-26, 1404/09/05

Registrant information

Name

Shabnam Shahrokh

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2025-11-22, 1404/09/01
Expected recruitment end date
2026-01-21, 1404/11/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effectiveness of three treatment regimens including a two-drug regimen of amoxicillin and venoprazone, a three-drug regimen of amoxicillin, venoprazone, and levofloxacin, and a four-drug regimen of esomeprazole, amoxicillin, metronidazole, and bismuth in eradicating Helicobacter pylori.

Public title
Comparing the effectiveness of three different treatment regimens in eradicating Helicobacter pylori
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age 18 to 70 years Definite diagnosis of Helicobacter pylori infection Willingness and ability to participate in the study and complete the treatment course
Exclusion criteria:
History of previous treatment for Helicobacter pylori eradication Taking antibiotics or proton pump inhibitors within the past four weeks Known allergy to any of the drugs used in the study Having significant underlying diseases or comorbidities
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
3
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **150**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, the randomization process will be performed as a random block with an individual randomization unit. The randomization sequence will be generated using statistical software and computer-generated random numbers to minimize the possibility of bias. The block sizes will be chosen as variables to reduce the predictability of allocations. After generating the randomization sequence, individuals will be assigned to three treatment groups in a 1:1:1 ratio. The randomization pattern will be performed without the use of stratification, and all participants will enter one of the three treatment arms based on a predetermined sequence. To ensure allocation concealment, the randomization sequence will be placed in opaque, numbered, and sealed envelopes, and the person responsible for enrolling participants will not have access to the contents of the envelopes; thus, the treatment group assignment for each participant will not be predictable before the envelope is opened. This method prevents premature sequence disclosure and bias, making the randomization process completely safe and reliable.
Blinding (investigator's opinion)
Single blinded
Blinding description
In this study, blinding is performed in a single-blind manner, with only the outcome assessor being blinded to the type of intervention received by the participants. Participants, prescribing physicians, the principal investigator, and the treatment team are aware of the type of treatment regimen each participant is receiving, and blinding is not possible or necessary for these groups. To ensure blinding of the outcome assessor, stool antigen test samples collected 6 to 8 weeks after the end of treatment are sent to the laboratory unit with anonymous codes and without mentioning the type of treatment regimen. The outcome assessor only records the test results and has no access to information related to group allocation. This method prevents any bias in recording the primary outcome of the study and maintains the single-blind nature of the study.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee, Institute of Gastroenterology and Liver Diseases, Shahid Beheshti Univers
Street address
Arabi street, Velenjak
City
Tehran
Province
Tehran
Postal code
193954631
Approval date
2025-09-22, 1404/06/31
Ethics committee reference number
IR.SBMU.RIGLD.REC.1404.017

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
Helicobacter pylori eradication
Timepoint
8 weeks after the start of the intervention
Method of measurement
Stool antigen test

Secondary outcomes

1

Description
Side effects
Timepoint
During the 14-day treatment period
Method of measurement
Clinical history

Intervention groups

1

Description
Intervention group: Two-drug regimen including amoxicillin 1 gram twice daily and venoprazan 20 mg twice daily for 14 days. All drugs are products of Abidi Company.
Category
Treatment - Drugs

2

Description
Intervention group: Triple-drug regimen including amoxicillin 1 g twice daily, venoprazan 20 mg twice daily, and levofloxacin 500 mg once daily for 14 days.All drugs are products of Abidi Company.
Category
Treatment - Drugs

3

Description
Intervention group: OMAB regimen includes esomeprazole 40 mg twice daily, amoxicillin 1 g twice daily, metronidazole 500 mg twice daily, and bismuth 240 mg twice daily for 14 days.All drugs are products of Abidi Company.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Gastroenterology clinic, Taleghani Hospital, Tehran
Full name of responsible person
Shabnam Shahrokh
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mahbod Sianpanah

Position

Subspecialist

Latest degree

Subspecialist

Other areas of specialty/work

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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

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not 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

The data file related to the primary outcome, Helicobacter pylori eradication, will be shared in coded form. The study protocol, SPSS statistical analysis file, clinical study report, and other data will also be provided to other researchers upon request.

When the data will become available and for how long

After publishing the paper

To whom data/document is available

Researchers in the fields of Internal medicine and gastroenterology

Under which criteria data/document could be used

For research purposes and with attribution.

From where data/document is obtainable

connection with the corresponding authors Dr. Shabnam Shahrokh shabnamsharokh@gmail.com

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

Send an email to the responsible author and state the reason for the request.

Comments