Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Multicenter, Randomized, Allocation-Concealed, Assessor-Blinded Trial of Three H. pylori Eradication Regimens in Iranian Patients

Protocol summary

Study aim
To compare the clinical effectiveness of three Helicobacter pylori eradication regimens in Iranian adults

Design
Multicenter, Randomized, Allocation-Concealed, Assessor-Blinded Trial of Three H. pylori Eradication Regimens in 1230 Iranian Patients

Settings and conduct
Patients with H.pylori infection who visit one of the 13 study centers during the study will receive (if eligible)treatment packages according to a random code assigned by the website

Participants/Inclusion and exclusion criteria
Inclusion criteria: Adult patients with Indications for H. pylori treatment Exclusion criteria: Previous treatment, Use of Antibiotics or bismuth 4 weeks or PPIs 2 weeks prior, Gastric surgery, Cancer or severe systemic disease, Known Allergy, Pregnancy or lactation

Intervention groups
Intervention Group 1: The optimized bismuth quadruple regimen for 14 days: 1- Esomeprazole (Ezonium, Abidi Pharmaceutical) 20 mg one capsule every 12 hours, 2- Bismuth subcitrate (Alborz Darou) 120 mg one tablet every 6 hours, 3- Tetracycline (Iran Darou) 250 mg two capsules every 6 hours, 4- Metronidazole (Cosar Pharmaceutical) 500 mg one tablet every 6 hours Intervention Group 2 :PCAB based dual regimen for 14 consecutive days:1- Vonoprazan (PHORIZE, Abide Pharmaceutical) 20 mg one tablet every 12 hours, 2- Amoxicillin (Cosar Pharmaceutical) 500 mg two tablets every 8 hours Intervention group 3 : The modified bismuth quadruple regimen for 14 days: 1- Esomeprazole (Ezonium, Abidi Pharmaceutical) 40 mg one capsule every 12 hours, 2- Bismuth subcitrate (Alborz Darou) 120 mg two tablets every 12 hours, 3- Amoxicillin (Cosar Pharmaceutical) 500 mg two tablets every 12 hours, 4- Metronidazole (Cosar Pharmaceutical) 500 mg one tablet every 12 hours

Main outcome variables
Primary outcome: eradication of Helicobacter pylori, defined as negative stool antigen six weeks after completion of treatment

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200128046294N4**
Registration date: **2025-10-26, 1404/08/04**
Registration timing: **prospective**

Last update: **2025-10-26, 1404/08/04**
Update count: **0**

Registration date
2025-10-26, 1404/08/04

Registrant information

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-11-06, 1404/08/15

Expected recruitment end date
2026-04-19, 1405/01/30

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Multicenter, Randomized, Allocation-Concealed, Assessor-Blinded Trial of Three H. pylori Eradication Regimens in Iranian Patients

Public title

Clinical trial for Helicobacter pylori eradication regimens

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Adult patients(18–60 years old) Indication of H.pylori treatment (Peptic ulcer disease, Marginal zone B-cell lymphoma MALT type, Uninvestigated dyspepsia in patients who are under the age of 60 years, Functional dyspepsia, Adult household members of individuals who have a positive non-serological test for H. pylori, Patients taking long term NSAIDs or starting long-term treatment with aspirin, Patients with unexplained iron deficiency anemia, Patients with idiopathic autoimmune thrombocytopenic purpura, Primary and secondary prevention of gastric adenocarcinoma, Current or history of gastric premalignant conditions, Persons with a first degree relative with gastric cancer, Syndromes associated with an increased risk for gastric cancer, Patients with autoimmune gastritis) Informed consent for participating in the study

Exclusion criteria:

Prior eradication of h.pylori Taking antibiotics, or bismuth-containing medications within four weeks and proton pump inhibitors (PPIs) within two weeks prior to study entry History of gastric surgery Cancer or severe systemic disease Known sensitivity to drugs used in the treatment protocol Pregnancy breastfeeding

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **1230**

Randomization (investigator's opinion)

Randomized

Randomization description

An online system (site) will be designed for this study and implemented on the servers of the Gastroenterology and Liver Research Institute. After reviewing the entry criteria and obtaining informed consent, this system will include patient information and assigning drug package codes. Each physician participating in this project can log in to the site using his or her own code and enter patient information. This system will automatically notify the physician of the specific package number for each patient only after the final registration of the first form of the patient questionnaire. Patients will be assigned to three treatment regimens in a ratio of 1:1:1 and based on a randomized block method with a block size of 6. The randomization of this study will be designed using R software by an individual independent of the executive team. The generated random sequence will be stored centrally and secretly at the central study site. All medications will be prepared in sealed and coded packages and delivered to the centers. These packages are standardized in terms of appearance, size, color, and shape so that there is no distinction between the packages. In the allocation process, the doctor only receives the package number from the system and delivers the package to the patient without knowing the contents inside. In each package, the method of taking the drugs in the package will be fully mentioned along with the necessary explanations and possible side effects of the drugs. Also, contact numbers will be provided for the patients of the plan to communicate with the treating physician and the central study and consultation team regarding the drugs and their side effects.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Digestive Disease Research Institute - Tehran University of Medical Sciences

Street address

Digestive Disease Research Institute, Shariati Hospital, Kargar Street, Tehran

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Province

Tehran

Postal code

1411713135

Approval date

2025-09-16, 1404/06/25

Ethics committee reference number

IR.TUMS.DDRI.REC.1404.014

Health conditions studied

1

Description of health condition studied

Helicobacter pylori

ICD-10 code

B98.0

ICD-10 code description

Helicobacter pylori [H.pylori] as the cause of diseases classified to other chapters

Primary outcomes

1

Description

Eradication of Helicobacter pylori infection

Timepoint

Time of positive Helicobacter pylori test at the beginning of treatment and eradication test six weeks after completion of the fourteen day treatment period

Method of measurement

Negative H. pylori antigen in stool antigen test or negative Urea breath test

Secondary outcomes

1

Description

Percentage of patients experiencing at least one adverse event during the study

Timepoint

Six weeks after completing the fourteen-day drug treatment

Method of measurement

Structured clinical interview and completion of an adverse event report form with physician

2

Description

Percentage of adherence to each medication

Timepoint

6 weeks after completion of treatment at the final visit

Method of measurement

The patient hands over all of his or her medications during the final visit, and the number of each medication the patient has taken will be recorded on the website.

Intervention groups

1

Description

Intervention Group 1: The optimized bismuth quadruple regimen for 14 days: 1- Esomeprazole (Ezonium, manufactured by Abidi Pharmaceutical Company), 20 mg, one capsule every 12 hours 2- Bismuth subcitrate (manufactured by Alborz Darou Company), 120 mg, one tablet every 6 hours 3- Tetracycline (manufactured by Iran Darou Company), 250 mg, two capsules every 6 hours 4- Metronidazole (manufactured by Cosar Pharmaceutical Company), 500 mg, one tablet every 6 hours

Category

Treatment - Drugs

2

Description

Intervention Group 2 :Potassium-competitive acid blocker (PCAB)-based dual regimen for 14 consecutive days:1- Vonoprazan (PHORIZE, manufactured by Abide Pharmaceutical Co.), 20 mg, one tablet every 12 hours 2- Amoxicillin (manufactured by Cosar Pharmaceutical Co.), 500 mg, two tablets every 8 hours

Category

Treatment - Drugs

3

Description

Intervention group 3 : The modified bismuth quadruple regimen for 14 days: 1- Esomeprazole (Ezonium, produced by Abidi Pharmaceutical Company), 40 mg, one capsule every 12 hours 2- Bismuth subcitrate (produced by Alborz Darou Company), 120 mg, two tablets every 12 hours 3- Amoxicillin (produced by Cosar Pharmaceutical Company), 500 mg, two tablets every 12 hours 4- Metronidazole (produced by Cosar Pharmaceutical Company), 500 mg, one tablet every 12 hours

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

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Sponsors / Funding sources

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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
Tehran University of Medical Sciences

Proportion provided by this source
1

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

2

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
Dr. Abidi Pharmaceuticals

Proportion provided by this source
99

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
Industry

Person responsible for general inquiries

Contact

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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
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is 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
All the data will be published after the study is completed. Individual identifiers will be removed when approval by the scientific team. IPD sharing will be limited to data on primary outcome, secondary outcomes, and demographic information.
When the data will become available and for how long
Access begins: after publication of the original article
To whom data/document is available
Researchers affiliated with universities or non-profit scientific institutions. Researchers in the fields of medicine, epidemiology, public health, and pharmacology
Under which criteria data/document could be used
For independent scientific analyses, systematic reviews or meta-analyses
From where data/document is obtainable
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What processes are involved for a request to access data/document
The official request has to be sent to the email address provided. The research team will respond within 30 days. If approved, access will be provided under a formal

agreement (MOU).

Comments