# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

10 Jun 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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Tehran

**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

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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**

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**Web page address**
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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**

**Name of organization / entity**
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**Full name of responsible person**
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**Position**
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**Latest degree**
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## Person responsible for scientific inquiries

**Contact**
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## Person responsible for updating data

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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**
Address: Digestive Diseases Research Center, Digestive Diseases Research Institute, Tehran University of Medical Sciences, Tehran, Iran Email: molaei.mahdi78@gmail.com, anahitasadeghim@gmail.com Phone: 09966993304
**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**