Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of the effectiveness of administering amoxicillin 3 or 4 times daily in triple-drug regimens containing esomeprazole, bismuth, and amoxicillin for eradication of Helicobacter pylori in patients with this infection

Protocol summary

Study aim
Comparison of 3 or 4 times daily amoxicillin administration in the eradication of H. pylori in a 14-day regimen of bismuth triple therapy

Design
The clinical trial with two parallel groups, single blind, randomized, phase 3 is conducted on 200 patients. For randomization, rand function of Excel software was used and 100 patients were placed in each group.

Settings and conduct
In this study, 200 people with dyspepsia who refer to the gastroenterology clinic of Imam Sari Hospital, who have an indication for endoscopy and the presence of Helicobacter pylori is proven in the biopsy, and who have not previously received a Helicobacter pylori eradication regimen, are assigned to groups A or B based on a random table. The treating physician is aware of the type of treatment, but the others in the research group are unaware.

Participants/Inclusion and exclusion criteria
Patients over 18 years of age who undergo endoscopy and are confirmed to have Helicobacter pylori and have not been treated for this microbe will be included in the study. Patients with underlying medical conditions, previous anti-H. pylori treatment, history of gastric surgery, and history of gastrointestinal malignancy will be excluded from the study.

Intervention groups
In both groups, patients will receive bismuth 240 mg three times daily and esomeprazole 40 mg twice daily for 14 days. However, the dose of amoxicillin in group A will be 1 g three times daily and in group B 750 mg four times daily.

Main outcome variables
the eradication rate of Helicobacter pylori

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20240507061691N1**
Registration date: **2025-02-09, 1403/11/21**
Registration timing: **registered_while_recruiting**

Last update: **2025-02-09, 1403/11/21**
Update count: **0**

Registration date
2025-02-09, 1403/11/21

Registrant information
Name
Masoud Hosseini
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2025-02-03, 1403/11/15
Expected recruitment end date
2025-07-23, 1404/05/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date

empty

Scientific title
Comparison of the effectiveness of administering amoxicillin 3 or 4 times daily in triple-drug regimens containing esomeprazole, bismuth, and amoxicillin for eradication of Helicobacter pylori in patients with this infection

Public title
Comparison of 3 or 4 times daily amoxicillin administration in a triple therapy for Helicobacter pylori eradication.

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Subjects with dyspepsia who undergo endoscopy Biopsy during endoscopy confirms the presence of Helicobacter pylori For the first time, a Helicobacter pylori eradication regimen is prescribed for them.

Exclusion criteria:
Unwillingness to participate in the study Patients who are taking anticoagulants, corticosteroids or ketoconazole at the same time Patients who have a history of stomach surgery Patients who have a history of heart failure, lung disease, chronic kidney failure, liver disease (cirrhosis or chronic hepatitis for any reason) or a history of cancer Consumption of alcoholic beverages in any amount The presence of any type of malignancy History of drug sensitivity to the drugs of this study History of H. pylori eradication regimens at any time Pregnancy and breastfeeding

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **200**

Randomization (investigator's opinion)
Randomized

Randomization description
Random allocation will be done by block method (Randomization Block) with a block size of four and using Sealed Envelope online software at the address https://www.sealedenvelope.com at an individual level and by an Biostatistician researcher who is a member of the research team. In this site, which is an online software for creating random allocation, the create list option is selected through the randomization menu, and then the required parameters such as groups A and B, the number of blocks, which is 4, and the total number of samples will be entered. And finally the random allocation list will be created. A sealed non-transparent envelope will be used for concealment. Researchers enroll eligible participants after the baseline assessment, then remove and open each envelope in the order that corresponds to the participant's initial assessment order, and assign the eligible participant to either the intervention group or the control group.

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, the care provider, investigator, outcome assessor, and safety committee are the physicians who are implementing the plan and are not blinded to the prescribed medication regimen. The participant and data analyst are blinded.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Imam Khomeini Hospital of Mazandaran University of Medical Sciencesf

Street address
No. 12, Iranzamin Alley, Amir Mazandarani Ave.,

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Sari

Province
Mazandaran

Postal code
4815659411

Approval date
2024-03-04, 1402/12/14

Ethics committee reference number
IR.MAZUMS.IMAMHOSPITAL.REC.1403.017

Health conditions studied

1

Description of health condition studied
Helicobacter Pylori Infection

ICD-10 code
B98.0

ICD-10 code description
Helicobacter pylori [H.pylori] as the cause of diseases

Primary outcomes

1

Description
Helicobacter pylori eradication rate in treatment groups

Timepoint
4 weeks after completion of treatment

Method of measurement
Stool Helicobacter Pylori Antigen

Secondary outcomes

1

Description
Drug compliance rate in treatment groups
Timepoint
Fifteenth day from the start of treatment
Method of measurement
The medication bag is checked and if more than 90% of the medication has been consumed, it is considered excellent acceptance.

2

Description
Side effects in treatment groups
Timepoint
If during treatment (14 days) there are severe complications (drug complications prevent daily life), the patient will make a phone call to the clinical caregiver. If there are no severe complications, the patient will be visited on day 15 and complications will be assessed.
Method of measurement
Phone calls and visit

Intervention groups

1

Description
First intervention group: Patients in this group receive amoxicillin capsules (Farabi Company) 1 gram half an hour after breakfast, lunch and dinner; bismuth subcitrate tablets (Pursina Company) 240 mg half an hour before breakfast, lunch and dinner; and esomeprazole capsules (Abidi Company) 40 mg half an hour before breakfast and dinner for 14 days.
Category
Treatment - Drugs

2

Description
Second intervention group: Patients in this group receive amoxicillin capsules (Farabi Company) 750 mg half an hour after breakfast, lunch, dinner and late at night; bismuth subcitrate tablets (Pursina Company) 240 mg half an hour before breakfast, lunch and dinner; and esomeprazole capsules (Abidi Company) 40 mg half an hour before breakfast and dinner for 14 days.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
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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
Mazandaran 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
Mazandaran University of Medical Sciences

Full name of responsible person
Masoud Hosseini
Position
Gastroenterology Fellowship
Latest degree
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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
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
After de-identifying the participants in the study, the information related to the results of the interventions as well as the possible side effects of the intervention will be published according to the method of the intervention.
When the data will become available and for how long
The access period starts 1 month after the results are published
To whom data/document is available
The data will be available only to researchers working in academic and scientific institutions
Under which criteria data/document could be used
The data can be obtained only to compare and check the effect of different treatment regimens. The data related to the acceptance rate of different treatment regimens and the amount of side effects in each treatment regimen can be received.
From where data/document is obtainable
masoud.hosseini@mazums.ac.ir
What processes are involved for a request to access data/document
After reviewing the request, the data will be sent within a maximum period of one week
Comments