Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Aug 2026

Evaluation and comparison of the efficacy of triple therapies regimens containing bismuth with high dose and different doses of amoxicillin for eradicating Helicobacter pylori infection

Protocol summary

Study aim

Determination of H. pylori eradication with a 14-day regimen containing high doses of amoxicillin Determination of H. pylori eradication with a 14-day regimen containing moderate dose of amoxicillin Determining and comparing the acceptance of treatment by patients during treatment Determining and comparing the demographic characteristics of patients and evaluating their effect on H. pylori eradication Determining and comparing endoscopic findings in patients Determining the relationship between each endoscopic/demographic characteristic with H. pylori eradication Determining and comparing the severity of drug side effects in the two groups Determining and comparing drug discontinuation

Design

Demographic information of patients will be recorded in the questionnaire. At the end of treatment, patients are visited and asked about the side effects of treatment, the severity of side effects (uncomplicated, mild, moderate, and severe), and the compliance rate of treatment (good, moderate, and poor). Eight weeks after the end of treatment, the eradication rate of H. pylori is evaluated using the Fecal H. pylori Antigen method.

Settings and conduct

Imam Khomeini Hospital, Sari

Participants/Inclusion and exclusion criteria

Individuals over 18 years with dyspepsia who were indicated for the eradication of H. pylori and had not previously received eradication treatment are randomly assigned to the study. Patients with a history of chronic diseases, malignancies, and gastric surgery are excluded.

Intervention groups

The first group (high dose group): amoxicillin 1 gr TDS, bismuth 240 mg TDS, and esomeprazole 40 mg bid for 14 days The second group (moderate dose group): amoxicillin 750 mg TDS, bismuth 240 mg TDS, and esomeprazole 40 mg BID for 14 days

Main outcome variables

Stool Ag test result Drug acceptance and Side effects rate

General information

Reason for update

Acronym

EAB

IRCT registration information

IRCT registration number: **IRCT20210518051335N1**
Registration date: **2021-10-28, 1400/08/06**
Registration timing: **prospective**

Last update: **2021-10-28, 1400/08/06**
Update count: **0**

Registration date

2021-10-28, 1400/08/06

Registrant information

Name

Hafez Tirgar Fakheri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3337 4977

Email address

hafezfakheri@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-22, 1400/10/01

Expected recruitment end date

2023-01-21, 1401/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation and comparison of the efficacy of triple therapies regimens containing bismuth with high dose and different doses of amoxicillin for eradicating Helicobacter pylori infection

Public title

Evaluation and comparison of the efficacy of triple therapies regimens containing esomeprazole and different doses of amoxicillin and bismuth for eradicating Helicobacter pylori infection in Sari

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria:

Patients have H. pylori eradication indication based on endoscopic evidence Patients with positive Rapid urease test Patients with positive histology of H. pylori infection

Exclusion criteria:

Age under 18 years Reluctance to participate in the study Pregnancy and lactation Patients taking concomitant anticoagulants, corticosteroids or ketoconazole. Patients with a history of gastric surgery Patients with 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 alcohol in any amount The presence of any type of malignancy History of drug allergy to the drugs in this study History of H. pylori eradication regimens at any time before this study

Age

From **18 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **200**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are randomly randomized into blocks of 10 patients by a computer program and entered into the corresponding group of pre-prepared sets of numbers, respectively.

Blinding (investigator's opinion)

Double blinded

Blinding description

Depending on the diagnosis, patients will undergo eradication study and treatment, but will not be informed of the type of treatment (receiving the first group or the second group). The information of the patients of the two groups, with a non-specific name that is a definition of the study groups (for example, groups A and B) and only the main researcher knows the definition (B: high dose group and A: medium-dose group), will be available to the analyzer. Therefore, the analyzer is not aware of the type of drugs received in each group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Imam Hospital of Sari - Mazandaran University of Medical Sciences (Research Ethics Committee)

Street address

Imam hospital, Razi street

City

ساری

Province

Mazandaran

Postal code

816633131

Approval date

2021-01-27, 1399/11/08

Ethics committee reference number

IR.MAZUMS.IMAMHOSPITAL.REC.1399.092

Health conditions studied

1

Description of health condition studied

H. 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

H. pylori eradication

Timepoint

At least the eighth week after starting treatment

Method of measurement

stool examination

Secondary outcomes

1

Description
Drug compliance rate
Timepoint
8th week of study
Method of measurement
questionnaire

2

Description
severity of drug side effects
Timepoint
8th week of study
Method of measurement
questionnaire

Intervention groups

1

Description
High dose group: Patients receive amoxicillin 1 gr tds, bismuth 240 mg tds and omeprazole 40 mg bid for 14 days.
Category
Treatment - Drugs

2

Description
Medium dose group: Patients receive amoxicillin 750 mg tds, bismuth 240 mg tds and omeprazole 40 mg bid for 14 days.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital, Sari
Full name of responsible person
Hafez Tirgar Fakheri
Street address
Razi street, Imam Khomeini Hospital
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4816633131
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Majid Saeedi
Street address
Mazandaran University of Medical Sciences, Valiasr Highway, Joibar three ways, Imam Square, Sari
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Phone
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Email
majsaeedi@gmail.com
Grant name
Deputy of research and technology
Grant code / Reference number
7062
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
Hafez Tirgar Fakheri
Position
Professor
Latest degree
Subspecialist
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Others
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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 data can be shared when participants are not identifiable
When the data will become available and for how long
Ability to access data 6 months after publishing the results
To whom data/document is available
The data will be available to academic researchers and non-academic physicians
Under which criteria data/document could be used
Perform other analyzes and extract more results
From where data/document is obtainable
Please refer to the e-mail address of the responsible author
What processes are involved for a request to access data/document
Submit a request to the Deputy of research and technology of the University / Refer the request to the relevant author of the project
Comments