Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparing the efficacy of the bismuth-based quadruple therapy containing a high dose of metronidazole with a concomitant regimen containing clarithromycin for eradicating Helicobacter pylori infection

Protocol summary

Study aim
Determining and comparing H. pylori eradication with bismuth quadruple therapy containing high doses of metronidazole with concomitant quadruple regimen

Design
A clinical trial with two intervention groups, with parallel groups, double-blind, randomized, phase 2-3 on 200 patients. A computer program was used for randomization.

Settings and conduct
Patients with the indication of H. pylori eradication in Imam Khomeini Hospital Sari are randomly assigned to two drug groups A and B. 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.

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 A group (high dose metronidazole): amoxicillin 1 gram twice a day, metronidazole 1 gram twice a day, bismuth 240 milligrams twice a day, and pantoprazole 40 milligrams twice a day for 14 days. The B group (concomitant): amoxicillin 1 gram twice a day, metronidazole 500 milligrams twice a day, clarithromycin 500 milligrams twice a day, and pantoprazole 40 milligrams twice a day for 14 days

Main outcome variables
H. pylori eradication

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200915048726N3**
Registration date: **2023-11-25, 1402/09/04**
Registration timing: **prospective**

Last update: **2023-11-25, 1402/09/04**
Update count: **0**

Registration date
2023-11-25, 1402/09/04

Registrant information

Name
Arash kazemi visri

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 11 3337 7176

Email address
arash_6z@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-12-23, 1402/10/02

Expected recruitment end date
2024-02-19, 1402/11/30

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the efficacy of the bismuth-based quadruple therapy containing a high dose of metronidazole with a concomitant regimen containing clarithromycin for eradicating Helicobacter pylori infection

Public title

Comparing the efficacy of the bismuth-based quadruple therapy containing a high dose of metronidazole with a concomitant regimen containing clarithromycin for eradicating Helicobacter pylori infection

Purpose

Treatment

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

2-3

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 6 and 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 (Bismuth-containing quadruple and B: Concomitant quadruple), 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

Sari

Province

Mazandaran

Postal code

816633131

Approval date

2022-10-18, 1401/07/26

Ethics committee reference number

IR.MAZUMS.IMAMHOSPITAL.REC.1401.035

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

Helicobacter pylori eradicating

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
Intervention group: The A group (high dose metronidazole): amoxicillin 1 gr BD, metronidazole 1 gr BD, bismuth 240 mg BD, and pantoprazole 40 mg BD for 14 days
Category
Treatment - Drugs

2

Description
Intervention group: The B group (concomitant): amoxicillin 1 gr BD, metronidazole 500 mg BD, clarithromycin 500 mg BD, and pantoprazole 40 mg BD for 14 days
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital - Sari
Full name of responsible person
Arash Kazemi Visari
Street address
Imam Khomeini Hospital., Razi Ave
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Pedram Ebrahimnejad
Street address
Mazandaran University of Medical Sciences, Valiasr Highway, Joibar three ways, Imam Square
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Phone
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Email
pebrahimnejad@mazums.ac.ir
Grant name
Grant code / Reference number
۱۴۵۰۷
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
Arash Kazemi
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
Others
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Position
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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
Yes - There is 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
No - There is not 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 Deputy of Research and Technology of the University of Mazandaran University of Medical Sciences (via automation application or e-mail address, ebrahimnejad@mazums.ac.ir).

What processes are involved for a request to access data/document
The applicant submits a request for documents or data files related to this trial (which contain the applicant's e-mail address or mailing address) to the Deputy of Research and Technology of the University of Mazandaran University of Medical Sciences (via automation application or e-mail address, ebrahimnejad@mazums.ac.ir). If approved, this request will be referred to the responsible author of the project, Dr. Arash Kazemi. Then the data will be sent to the declared address.

Comments