Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 May 2026

Comparison of high-dose dual therapy and bismuth- containing quadruple therapy as a standard first line treatment in eradication of Helicobacter pylori infection

Protocol summary

Study aim
Comparison of high-dose dual therapy and bismuth-containing quadruple therapy as a standard first line treatment in eradication of Helicobacter pylori infection

Design
The clinical trial has two intervention groups, the selection of patients with H.pylori infection will be assigned Consecutive non-probability, and two intervention groups will be assigned randomly (using a table of random numbers)

Settings and conduct
the number of 206 patients referring to the gastroenterology clinic of Loqman Hospital during the mentioned period who are eligible to enter the study are divided into 2 groups, the first group is treated with four standard drugs containing bismuth and the second group is treated with high dose dual therapy for 14 days. After 4 weeks, the effectiveness of the mentioned two treatment methods is compared by the laboratory method of examining the antigen of H.pylori in stool.

Participants/Inclusion and exclusion criteria
In this study, patients who were diagnosed with H.pylori infection, are included in the study. Patients are excluded from the study if they are pregnant or lactating and have an underlying disease that affects the study, as well as alcohol abuse, use of the mentioned drugs in the last 4 weeks.

Intervention groups
The first intervention group of patients receiving amoxicillin (1 gr 30 minutes after breakfast and dinner), pantoprazole (20 mg 30 minutes before breakfast and dinner), metronidazole (1 gr 30 minutes after breakfast and dinner), bismuth sub Citrate (240 mg 30 minutes before breakfast and dinner) for 14 days and The second intervention group receiving high-dose dual treatment regimen including amoxicillin (1 gr 30 minutes after each meal) and pantoprazole (40 mg 30 minutes before breakfast and dinner) for 14 days, considering were taken

Main outcome variables
Eradication rate of H.pylori infection

General information

Reason for update

Acronym
نام اختصاری مهار کننده پمپ پروتون یا Proton Pump Inhibitors است. PPI سه حرف

IRCT registration information
IRCT registration number: **IRCT20221016056190N1**
Registration date: **2023-01-15, 1401/10/25**
Registration timing: **retrospective**

Last update: **2023-01-15, 1401/10/25**
Update count: **0**

Registration date
2023-01-15, 1401/10/25

Registrant information

Name
Maryam Abbasi
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-03-21, 1400/01/01

Expected recruitment end date

2022-02-20, 1400/12/01

Actual recruitment start date

2021-10-23, 1400/08/01

Actual recruitment end date

2022-03-16, 1400/12/25

Trial completion date

2022-03-16, 1400/12/25

Scientific title

Comparison of high-dose dual therapy and bismuth-containing quadruple therapy as a standard first line treatment in eradication of Helicobacter pylori infection

Public title

bismuth- containing quadruple and high-dose dual therapy in eradication of Helicobacter pylori infection

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with chronic gastritis with or without improved PUD caused by Helicobacter pylori Helicobacter pylori (+) determined by any of the rapid urease test and histopathology, urease breath test, fecal antigen test Patients who have not received Helicobacter pylori eradication treatment

Exclusion criteria:

Allergy to the drugs used in the study Use of PPIs, H2 receptor antagonists, antibiotics, bismuth or probiotics in the last 4 weeks before entering the study Smoking and alcohol abuse The presence of underlying disease or conditions such as liver disease, cardiovascular disease, lung disease, metabolic disease, or malignant tumor that may affect the study Pregnant or lactating female patients Performing esophageal or gastric surgery procedures in the past Incomplete follow-up or low acceptance capacity of patients in treatment during the study

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **200**

Actual sample size reached: **206**

Randomization (investigator's opinion)

Randomized

Randomization description

The selection of patients with Helicobacter pylori infection was done in a non-randomized manner and their division into two intervention groups was done randomly (using a table of random numbers) after considering confounding variables.In the table of random numbers, the direction of reading the table numbers was determined from the top and the left side, and then even numbers were considered for the intervention of the first group and odd numbers were considered for the intervention of the second group. And the second was specified.

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 Shahid beheshti University of Medical Sciences

Street address

No.21 ,Valizadeh St, Gisha Ave, Tehran, Iran

City

tehran

Province

Tehran

Postal code

1447973850

Approval date

2021-10-12, 1400/07/20

Ethics committee reference number

IR.SBMU.MSP.REC.1400.441

Health conditions studied

1

Description of health condition studied

Eradication of Helicobacter pylori infection

ICD-10 code

B98.0

ICD-10 code description

هلیکوباکتر پیلوری به عنوان عامل بیماری ها که در فصل های دیگر طبقه بندی می شود

Primary outcomes

1

Description

Eradication of Helicobacter pylori infection

Timepoint

4 weeks after receiving two treatment regimens, the eradication rate of Helicobacter pylori in two groups is compared

Method of measurement

Laboratory method of testing Helicobacter pylori antigen in stool

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The first intervention group was treated with four standard medicines containing bismuth, including amoxicillin (1 gram 30 minutes after breakfast and dinner), pantoprazole (20 mg 30 minutes before breakfast and dinner), metronidazole (1 gram 30 minutes after breakfast and dinner), bismuth sub Citrate (240 mg 30 minutes before breakfast and dinner) is placed for 14 days.
Category
Treatment - Drugs

2

Description
Intervention group: The second intervention group is treated with two high-dose drugs including amoxicillin (1 gram 30 minutes after each meal including breakfast, lunch and dinner) and pantoprazole (40 mg 30 minutes before breakfast and dinner) for 14 days.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
بیمارستان لقمان حکیم
Full name of responsible person
shahriar nikpour
Street address
Kamali St
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Postal code
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Fax
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Web page address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
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?
No
Title of funding source
does not have
Proportion provided by this source
1
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
Other

Person responsible for general inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Maryam Abbasi
Position
Resident of internal medicine
Latest degree
Medical doctor
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
Undecided - It is not yet known if there will be 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
Study data related to the main outcome and side effects reviewed after de-identification of subjects can be shared with other researchers

When the data will become available and for how long
6 months after the results are published

To whom data/document is available
Researchers of academic and scientific institutions

Under which criteria data/document could be used
The use of documentation and data analysis for other scientific research is allowed for other researchers

From where data/document is obtainable
By email to the following address abasimaryam1989@yahoo.com Maryam Abbasi

What processes are involved for a request to access data/document
After the request of the researchers, if at least 6 months have passed since the publication of the results, the data file will be sent after checking for use in the research

Comments