

# 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

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8827 9679

##### Email address

abasimaryam1989@yahoo.com

##### 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

##### City

tehran

##### Province

Tehran

##### Postal code

1333635445

##### Phone

+98 21 5541 9005

##### Fax

+98 21 5541 7547

##### Email

loghman.hospital@sbmu.ac.ir

##### Web page address

<https://lhmc.sbmu.ac.ir/>

## Sponsors / Funding sources

### 1

#### Sponsor

#### Name of organization / entity

Shahid Beheshti University of Medical Sciences

#### Full name of responsible person

maryam abbasi

#### Street address

No21, valizadeh St, Gisha Ave

#### City

tehran

#### Province

Tehran

#### Postal code

1447973850

#### Phone

+98 21 8875 1818

#### Email

abasimaryam1989@yahoo.com

#### 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

Internal Medicine

##### Street address

Unit 9 , No 21, Valizadeh St, Gisha Ave ,Tehran, Iran

##### City

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##### Province

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##### Postal code

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##### Phone

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##### Fax

##### Email

Abasimaryam1989@yahoo.com

## Person responsible for scientific 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

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## Person responsible for updating data

### 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**

Internal Medicine

**Street address**

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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**