

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 2026

Comparison of two quadruple regimens of amoxicillin, bismuth, levofloxacin and pantoprazole versus amoxicillin, clarithromycin, bismuth, pantoprazole to eradicate *Helicobacter pylori*

Protocol summary

Study aim

Comparison of two quadruple regimens of amoxicillin, bismuth, levofloxacin and pantoprazole versus amoxicillin, clarithromycin, bismuth, pantoprazole to eradicate *Helicobacter pylori*

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 196 patients. Software Random Allocation software will be used for randomization

Settings and conduct

This study is an interventional study and the study population is patients infected with *Helicobacter pylori* referred to a private clinic in Rasht. Patients who go to the clinic with a complaint of dyspepsia, reflux and meet the inclusion criteria will be admitted to the study after confirmation of consent. Patients will be randomly divided into 88 groups. The first group will be treated with clarithromycin, pantoprazole, bismuth tablets, and amoxicillin. The second group will receive a treatment regimen containing levofloxacin, pantoprazole, bismuth tablets and amoxicillin. Patients who have completed treatment will have another urease breath test to check for eradication of *Helicobacter pylori* 4 weeks after the end of treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: all patients with positive *Helicobacter pylori* test after endoscopy. Exclusion criteria: dissatisfaction with continued cooperation, drug sensitivity and severe side effects of contraindications to levofloxacin

Intervention groups

The intervention group will use a four-drug regimen containing levofloxacin 500 daily, pantoprazole 20 twice daily, bismuth tablets every 12 hours, and amoxicillin 1 g every 12 hours. The control group of the usual four-drug treatment group underwent clarithromycin 500 twice

daily, pantoprazole 20 twice daily, bismuth tablets every 12 hours and amoxicillin 1 g every 12 hours.

Main outcome variables

Eradication of *Helicobacter pylori*

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220306054205N1**

Registration date: **2022-04-18, 1401/01/29**

Registration timing: **retrospective**

Last update: **2022-04-18, 1401/01/29**

Update count: **0**

Registration date

2022-04-18, 1401/01/29

Registrant information

Name

Hamzehali Najafzadeh Shoki

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 3353 5116

Email address

dr.h.najafzade@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-22, 1400/10/01

Expected recruitment end date

2022-03-11, 1400/12/20

Actual recruitment start date

empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of two quadruple regimens of amoxicillin, bismuth, levofloxacin and pantoprazole versus amoxicillin, clarithromycin, bismuth, pantoprazole to eradicate *Helicobacter pylori*

Public title
The effect of two quadruple diets of amoxicillin, bismuth, levofloxacin and pantoprazole versus amoxicillin, clarithromycin, bismuth, pantoprazole in the treatment of *Helicobacter pylori*

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
All patients tested positive for *Helicobacter pylori* after endoscopy

Exclusion criteria:

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked

- Investigator
- Outcome assessor

Sample size
Target sample size: **196**

Randomization (investigator's opinion)
Randomized

Randomization description
The randomization method is 49 quadruple blocks in random blocks. The randomization method is 49 quadruple blocks in random blocks. After adopting the sequence list of blocks, this list is enclosed in a locked envelope and sealed in the clinic nursing center. Digestive research is maintained and read daily after the start of the study, and patients with inclusion criteria will receive their medication regimens according to the list.

Blinding (investigator's opinion)
Single blinded

Blinding description
This study is of Open Label type, because patients' medications are specific and have different colors and sizes. However, the researcher does not know the type of medication patients receive.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Guilan University of Medical Sciences

Street address

Namjoo St. Guilan University of Medical Sciences, Rasht13111-41937

City

Rasht

Province

Guilan

Postal code

41937-13111

Approval date

2021-03-10, 1399/12/20

Ethics committee reference number

IR.GUMS.REC.1399.649

Health conditions studied

1

Description of health condition studied

Helicobacter pylori [*H. pylori*] as the cause of diseases classified elsewhere

ICD-10 code

B96.81

ICD-10 code description

Helicobacter pylori [*H. pylori*] as the cause of diseases classified elsewhere

Primary outcomes

1

Description

The primary outcome variable in this study is the eradication of *Helicobacter pylori*. To evaluate the eradication of *Helicobacter pylori*, urease breath test will be performed again 4 weeks after the end of treatment. If the test is negative, the treatment will be considered successful.

Timepoint

4 weeks after the end of treatment

Method of measurement

Urease breath test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients in the intervention group will use a four-drug regimen containing levofloxacin 500 daily, pantoprazole 20 twice daily, bismuth tablets every 12 hours and amoxicillin 1 g every 12 hours.

Category

Treatment - Drugs

2

Description

Control group: In this study, the control group of the usual treatment group of four drugs under the treatment regimen with clarithromycin 500 twice daily, pantoprazole 20 twice daily, bismuth tablets every 12 hours and amoxicillin 1 gram every 12 hours will be given.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Private gastroenterology and liver clinic of Dr. Afshin Shafaghi

Full name of responsible person

Afshin Shafaghi

Street address

Rasht - Shahid Ansari Street - in front of Mellat Park

City

Rasht

Province

Guilan

Postal code

41937-13111

Phone

+98 13 3332 8101

Email

drafshinshafaghi@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Mohammadreza Naghipour

Street address

Rasht - Namjoo St. - Shahid Siadati St. - in front of Shahrivar Hospital - Vice Chancellor for Research and Technology

City

Rasht

Province

Guilan

Postal code

41937-13111

Phone

+98 13 3333 6394

Email

research@gums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Rasht 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

Rasht University of Medical Sciences

Full name of responsible person

Afshin Shafaghi

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

Street address

Namjoo St. Guilan University of Medical Sciences, Rasht

City

Rasht

Province

Guilan

Postal code

33111-41937

Phone

+98 13 3332 8101

Email

drafshinshafaghi@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Afshin Shafaghi

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

Street address

Rasht - Shahid Ansari Street - in front of Mellat Park

City

Rasht

Province

Guilan

Postal code

41937-13111

Phone

+98 13 3332 8101

Email

drafshinshafaghi@gmail.com

Person responsible for updating data**Contact****Name of organization / entity**

Rasht University of Medical Sciences

Full name of responsible person

Afshin Shafaghi

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

Street address

Rasht - Shahid Ansari Street - in front of Mellat Park

City

Rasht

Province

Guilan

Postal code

41937-13111

Phone

+98 13 3332 8101

Email

drafshinshafaghi@gmail.com

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available