Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 diets 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 Lable 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
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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
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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
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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