Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jun 2026

Comparison of effectiveness of moxifloxacin, amoxicillin and pantoprazole regimen with clarithromycin-based four-drug regimen for eradicating Helicobacter pylori infection

Protocol summary

Study aim

Comparison of effectiveness of moxifloxacin, amoxicillin and pantoprazole regimen with clarithromycin-based four-drug regimen for eradicating Helicobacter pylori infection

Design

Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3 on 246 patients. Randomization will be done in such a way that people are divided into two groups based on the first four-way random permutation completely randomly (by a person who was not involved in the study process).

Settings and conduct

The present study will be conducted as a double-blind randomized clinical trial on patients with confirmed Helicobacter infection referred to the clinic and endoscopy department of Imam Khomeini Hospital in Ahvaz in 1403. He receives the antibiotic regimen and his details are recorded in the questionnaire for further follow-up.

Participants/Inclusion and exclusion criteria

All people willing to participate in the study, over 18 years old, with a positive test for Helicobacter pylori and without a history of treatment for this disease will be included in the study, and people with a history of stomach surgery and treatment, pregnant and lactating people will not be included.

Intervention groups

In the intervention group, the regimen is based on moxifloxacin and in the control group, the standard four-drug regimen is based on clarithromycin.

Main outcome variables

Age; gender; therapy groups; drug side effects ; acceptance of medication; Eradication

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240128060832N1**
Registration date: **2024-02-24, 1402/12/05**
Registration timing: **prospective**

Last update: **2024-02-24, 1402/12/05**
Update count: **0**

Registration date

2024-02-24, 1402/12/05

Registrant information

Name

Amir Hooshang Bavarsad

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-03-20, 1403/01/01

Expected recruitment end date

2024-06-19, 1403/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of effectiveness of moxifloxacin, amoxicillin and pantoprazole regimen with clarithromycin-based four-drug regimen for eradicating Helicobacter pylori infection

Public title
Investigating the effect of moxifloxacin in Helicobacter infection

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age above 18 years All patients with PUD, peptic ulcer, non-ulcer dyspepsia and intestinal metaplasia (based on pathology samples) underwent endoscopic evaluation and H. pylori positive confirmation by Rapid urease test (RUT). No previous treatment of H. pylori infection Patient consent to participate in the study

Exclusion criteria:
Unwillingness to participate in the study Taking antibiotics or non-steroidal anti-inflammatory drugs (NSAID) in the last 4 weeks Allergy to any of the study drugs A history of gastric surgery or the presence of a serious concurrent disease such as cancer Pregnant or lactating women

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **246**

Randomization (investigator's opinion)
Randomized

Randomization description
People will be divided into two groups based on the first quadruple random permutation completely randomly (by a person who had no involvement in the study process). Also, matching will be done based on age and gender.

Blinding (investigator's opinion)
Double blinded

Blinding description
Blinding is done in such a way that the person who performs the randomization and allocation of people to groups will not have any information about the condition of the patients. The patient and the person who examines the results will not have any information about which group the people are placed in, and the study is conducted in a double-blind manner.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Jundi Shapur Ahvaz University of Medical Sciences

Street address
Vice President of Research and Technology Development, Esfand St., Jundishapur University of Medical Sciences, Golestan Blvd.,

City
Ahwaz

Province
Khouzestan

Postal code
6135715794

Approval date
2023-11-18, 1402/08/27

Ethics committee reference number
IR.AJUMS.REC.1402.419

Health conditions studied

1

Description of health condition studied
Helicobacter pylori infection

ICD-10 code
B98.0

ICD-10 code description
Helicobacter pylori [H.pylori] as the cause of diseases classified to other chapters

Primary outcomes

1

Description
Determination of positive or negative Helicobacter infection by fecal antigen test

Timepoint
Helicobacter test before and two weeks after treatment

Method of measurement
Helicobacter pylori fecal antigen

Secondary outcomes

1

Description
Drug side effects

Timepoint
During treatment and two weeks after treatment

Method of measurement
Registration in the patient's self-report questionnaire

2

Description
Acceptance of medication
Timepoint
During treatment and two weeks after treatment
Method of measurement
Registration in the patient's self-report questionnaire

Intervention groups

1

Description
Intervention group: Administration of amoxicillin 1000 mg every 12 hours, moxifloxacin 400 mg every 12 hours, and pantoprazole 40 mg every 12 hours for 10 days, followed by pantoprazole at a dose of 40 mg every twelve hours for four weeks.
Category
Treatment - Drugs

2

Description
Control group: Administration of clarithromycin 500 mg every 12 hours, amoxicillin 1000 mg every 12 hours, bismuth subcitrate 240 mg every 12 hours and pantoprazole 40 mg every 12 hours for 10 days, followed by pantoprazole at a dose of 40 mg every twelve hours. The watch lasts for four weeks.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital of Ahvaz
Full name of responsible person
Amir hooshang bavarsad
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Imam Khomeini Hospital ,24 Meter Street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Email
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Web page address
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Amir hooshang bavarsad
Position
Assistant specialist in gastroenterology and liver for adults
Latest degree
Specialist
Other areas of specialty/work
Internal Medicine
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No. 8, Mehr East Street, Kianpars Street
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Person responsible for scientific inquiries

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Position
Gastroenterology and hepatology assistant for adults

Latest degree
Specialist

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Person responsible for updating data

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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
Not applicable

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