

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)

Phone

+98 61 3333 4663

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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

Ahvaz

Province

Khuzestan

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

Street address

Imam Khomeini Hospital ,24 Meter Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

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Street address

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

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Email

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Web page address

https://www.ajums.ac.ir

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

Street address

No. 8, Mehr East Street, Kianpars Street

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Amir hooshang bavarsad

Position

Gastroenterology and hepatology assistant for adults

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Position

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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