Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 May 2026

Comparison of the efficacy of the amoxicillin and pantoprazole regimen with clarithromycin-based quadruple regimen for Helicobacter pylori eradication

Protocol summary

Study aim

Comparison the efficacy of the amoxicillin and pantoprazole regimen with clarithromycin-based quadruple regimen for Helicobacter pylori eradication

Design

This clinical trial with parallel groups, double-blinded randomized, will be conducted on 166 in patients with positive H.pylori infection. Assignment of patients to the study groups will be done by random-numbers table and using computer

Settings and conduct

From patients with confirm diagnosis of H. pylori infection referring to Imam Khomeini hospital, Ahvaz, total of 166 patients will be selected and randomly divided into 2 groups. The patients and experimenters will not know about type of treatment and patient grouping

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age above 18 years, confirm diagnosis of H. pylori infection by stool antigen test, no previous treatment of H. pylori infection, patient consent to participate in the study; Exclusion criteria: using antibiotics or nonsteroidal anti-inflammatory drugs (NSAIDs) in last 4 weeks, allergy to the studied drugs, history of gastric surgery or presence of a serious concomitant disease such as cancer, pregnant or lactating women

Intervention groups

Intervention group (dual regimen): amoxicillin 1000 mg every 12 hours and pantoprazole 40mg every 12 hours for 14 days and then pantoprazole 40 mg every 12 hours for 4 weeks will be prescribed. Control group (quadruple regimen): clarithromycin 500 mg every12 hours, amoxicillin 1000mg every 12 hours, bismuth subcitrate 240 mg every 12 hours and pantoprazole 40 mg every 12 hours for 14 days and then pantoprazole 40 mg every 12 hours for 4 weeks will be prescribed.

Main outcome variables

Presence of Helicobacter pylori infection (based on stool antigen test) 2 weeks after the end of treatment and presence of any complication of medication (nausea, vomiting, and allergic reactions)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211019052812N1**
Registration date: **2021-11-06, 1400/08/15**
Registration timing: **prospective**

Last update: **2021-11-06, 1400/08/15**
Update count: **0**

Registration date

2021-11-06, 1400/08/15

Registrant information

Name

Samira Mohammadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-22, 1400/09/01

Expected recruitment end date

2022-04-21, 1401/02/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the efficacy of the amoxicillin and pantoprazole regimen with clarithromycin-based quadruple regimen for Helicobacter pylori eradication

Public title
Comparison the amoxicillin and pantoprazole regimen with quadruple regimen for Helicobacter pylori eradication
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age more than 18 years Confirm diagnosis of H. pylori infection by stool antigen test No previous treatment of H. pylori infection Patient consent to participate in the study
Exclusion criteria:
Use of antibiotics or nonsteroidal anti-inflammatory drugs (NSAIDs) in the last 4 weeks allergy to any of the studied drugs History of gastric surgery or the presence of a serious concomitant disease such as cancer, Pregnant or lactating women
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **166**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be assigned into two groups by simple randomization method. Allocation of patients to the study groups will be done by random-numbers table and using computer, and on this basis patients will be included in one of the two treatment groups. The implementation of the random allocation sequence occurs without knowledge of which patient will receive which treatment.
Blinding (investigator's opinion)
Double blinded
Blinding description
Intervention (receiving dual therapy regimen or clarithromycin-based quadruple regimen) and patient evaluation will be carried out by a physician who is blinded to placement in treatment groups. Also patients and statistical analyzer will not know about patient grouping.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Ahvaz Jundishapur University of Medical Sciences
Street address
Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd.
City
Ahvaz
Province
Khouzestan
Postal code
6135733118
Approval date
2021-10-19, 1400/07/27
Ethics committee reference number
IR.AJUMS.HGOLESTAN.REC.1400.098

Health conditions studied

1

Description of health condition studied
Helicobacter pylori infection
ICD-10 code
B96.81
ICD-10 code description
Helicobacter pylori [H. pylori] as the cause of diseases classified elsewhere

Primary outcomes

1

Description
Presence of Helicobacter pylori infection
Timepoint
Two weeks after the end of treatment
Method of measurement
Assess the presence of infection based on Stool Antigen Test

Secondary outcomes

1

Description
Treatment complication
Timepoint
Patients clinical visits every two weeks and fallow up by phone call every week
Method of measurement
Presence of nausea, vomiting and any allergic reactions based on clinical information

Intervention groups

1

Description
Intervention group: (dual regimen): amoxicillin 1000 mg every 12 hours (Farabi pharmaceutical CO., Iran) and pantoprazole 40 mg every 12 hours (Tehranchemie CO., Iran) for 14 days and then pantoprazole 40 mg every 12 hours for 4 weeks will be prescribed for Helicobacter pylori eradication.
Category
Treatment - Drugs

2

Description
Control group: (quadruple regimen): clarithromycin (Loghman pharmaceutical CO., Iran) 500 mg every 12 hours, amoxicillin 1000 mg every 12 hours (Farabi pharmaceutical CO., Iran), bismuth subcitrate (Aria Co., Iran) 240 mg every 12 hours and pantoprazole 40 mg every 12 hours (Tehranchemie CO., Iran) for 14 days and then pantoprazole 40 mg every 12 hours for 4 weeks will be prescribed for Helicobacter pylori eradication.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Samira Mohammadi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Mohammad Baddvi
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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
Samira Mohammadi
Position
Resident
Latest degree
Specialist
Other areas of specialty/work
Internal Medicine
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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
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