

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Eradication Efficacy of high dose amoxicillin and PPI Compared with standard bismuth containing quadruple Therapy as a First Line Treatment of Helicobacter pylori

Protocol summary

Study aim

evaluation of easier antibiotic treatment regimen with fewer side effects in H.pilori treatment

Design

Clinical trial with control group, parallel group trial, phase 3 on 220 patients. Replacement randomization was used.

Settings and conduct

This is a randomized controlled clinical trial study conducted on 220 patients with Helicobacter Pylori infection referred to Imam Khomeini Hospital gastrointestinal clinic or attending office in Ahvaz. The patients were treated with one of two antibiotic regimens. The Eradication was determined by Stool antigen tests test at least 1 month after treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria were as follows: chronic gastritis with or without healed duodenal or stomach ulcer H. pylori positive determined by Rapid Urease Test or Urea Breath Test treatment-naïve patients for eradication of H. pylori infection Exclusion criteria: allergy to medications used in this clinical trial use of PPI, histamine H2-receptor antagonists, antibiotics, bismuth, or probiotics 4 weeks before initiating study, pregnancy or breastfeeding

Intervention groups

Control group: Bismuth containing Quadruple therapy { clarithromycin 500 mg and amoxicillin 1 g and bismuth 220mg all twice per day), a proton pump inhibitor (pantoprazole 40 mg twice daily) all for 14 days} Intervention group: amoxicillin 750mg QID and pantoprazole 40mg TDS for 14 days

Main outcome variables

Rate of eradication Helicobacter pylori ,Cost of treatment, Drugs side effect

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201007048956N1**

Registration date: **2020-11-09, 1399/08/19**

Registration timing: **retrospective**

Last update: **2020-11-09, 1399/08/19**

Update count: **0**

Registration date

2020-11-09, 1399/08/19

Registrant information

Name

Amin Sabbaghan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3336 0421

Email address

sabbaghanamin@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-25, 1398/06/03

Expected recruitment end date

2020-03-05, 1398/12/15

Actual recruitment start date

2019-09-11, 1398/06/20

Actual recruitment end date

2020-03-05, 1398/12/15

Trial completion date

2020-07-26, 1399/05/05

Scientific title

Eradication Efficacy of high dose amoxicillin and PPI

Compared with standard bismuth containing quadruple Therapy as a First Line Treatment of Helicobacter pylori

Public title
Treatment of Helicobacter pylori infection of the stomach

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 chronic gastritis with or without healed duodenal or stomach ulcer H. pylori positive determined by Rapid UreaseTest or Urea Breath Test treatment-naïve patients for eradication of H. pylori infection
Exclusion criteria:
 allergy to medications used in this clinical trial use of PPI, histamine H2-receptor antagonists, antibiotics, bismuth, or probiotics 4 weeks before initiating study pregnancy or breastfeeding

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
 Target sample size: **220**
 Actual sample size reached: **194**

Randomization (investigator's opinion)
Randomized

Randomization description
 In this study, we will use the Restricted randomization method of block randomization. Blockage is usually used to balance the number of samples allocated to each of the studied groups. This feature helps researchers to equalize the number of samples allocated to each of the studied groups in cases where intermediate analyzes are required during the sampling process. All blocks are the same size, and in this two-group experiment we will have 6 blocks (including 3 participants in the intervention group and 3 participants in the control group). Random allocation software software is also used to randomize random sequence production software (Random allocation software).

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of ahwaz University of Medical Sciences

Street address

Ground floor central organization of Ahwaz Jundishapur University, Glestani Street.

City

Ahwaz

Province

Khouzestan

Postal code

6133944753

Approval date

2019-12-07, 1398/09/16

Ethics committee reference number

IR.AJUMS.REC.1398.645

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

helicobacter pylori infection

Timepoint

45 days after intervention

Method of measurement

stool antigen test of helicobacter pylori

Secondary outcomes

1

Description

Reduce the cost of treatment

Timepoint

45 days

Method of measurement

Lower cost

2

Description

Less drug side effects

Timepoint

45 days

Method of measurement

Patient clinical sign

Intervention groups

1

Description

Intervention group: amoxicillin 750mg QID and pantoprazole 40mg TDS for 14 days

Category

Treatment - Drugs

2

Description

Control group: Bismuth containing Quadruple therapy { clarithromycin 500 mg and amoxicillin 1 g and bismuth 220mg all twice per day), a proton pump inhibitor (pantoprazole 40 mg twice daily) all for 14 days }

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emamkhomeini hospital

Full name of responsible person

Amin sabbaghan

Street address

24meter Ave., Azadegan, Emamkhomeini hospital

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6193673166

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mehdi Ahmadimoghadam

Street address

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ahmadi-m@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

Amin Sabbaghan

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

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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

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

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

Ahvaz University of Medical Sciences

Full name of responsible person

Amin Sabbaghan

Position

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Latest degree

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Other areas of specialty/work

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