

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 May 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-naive 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 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

#### 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, Glestan 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

##### City

Ahvaz

##### Province

Khuzestan

##### Postal code

6193673166

##### Phone

+98 61 9367 3111

##### Email

himam@ajums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Ahvaz University of Medical Sciences

##### Full name of responsible person

Mehdi Ahmadimoghadam

##### Street address

Ahwaz central medical sciences organization,golesan Ave.

##### City

ahwaz

##### Province

Khuzestan

##### Postal code

6135715794

##### Phone

+98 61 3373 8383

#### Email

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

##### Street address

No.۲۸,soghrat Ave.,amaniye Town

##### City

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##### Province

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##### Phone

+98 61 3336 0421

##### Fax

##### Email

Sabbaghanamin@yahoo.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Ahvaz University of Medical Sciences

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Amin Sabbaghan

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Professor

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**Person responsible for updating data****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

**Street address**

No.۲۸,soghrat Ave.,amaniye Town

**City**

Ahwaz

**Province****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