

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison between the two drug regimens of "Amoxicillin-Rifaximin-PPI" and "Amoxicillin-Clarithromycin-PPI" for the treatment of H.pylory infection

Protocol summary

Study aim

Comparison between the two drug regimens of "Amoxicillin-Rifaximin-PPI" and "Amoxicillin-Clarithromycin-PPI" for the treatment of H.pylory infection.

Design

Clinical trial with a control group and parallel groups, without blinding, without randomization, phase 4 on 86 patients.

Settings and conduct

86 patients with H. pylori infection who have not yet been treated to eradicate it, will be included in the study. Confirmation of H. pylori infection will be provided by rapid urease test or histological evaluation of antrum and gastric specimens by Giemsa staining.

Participants/Inclusion and exclusion criteria

Proof of H. pylori infection with rapid urease test or histological evaluation of gastric antrum and gastric body samples with Giemsa staining; patient's informed consent.

Intervention groups

Intervention group: A 14-day four-drug regimen containing rifaximin (rifaximin 500 mg, amoxicillin 1 g, Pantoprazole 40 mg and bismuth tablets, all twice a day)
Control group: Standard 14-day drug regimen (clarithromycin 500 mg, amoxicillin 1 g, pantoprazole 40 mg and bismuth tablets, all twice a day)

Main outcome variables

Eradication of H. pylori, evaluated by urine stool antigen test

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230902059322N1**

Registration date: **2023-11-02, 1402/08/11**
Registration timing: **registered_while_recruiting**

Last update: **2023-11-02, 1402/08/11**

Update count: **0**

Registration date

2023-11-02, 1402/08/11

Registrant information

Name

Zahra Vaez Mousavi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3551 4025

Email address

vaezmousavi@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-06, 1402/06/15

Expected recruitment end date

2023-12-06, 1402/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between the two drug regimens of "Amoxicillin-Rifaximin-PPI" and "Amoxicillin-Clarithromycin-PPI" for the treatment of H.pylory infection

Public title

Comparison between the two drug regimens for the treatment of H.pylory infection

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Proof of H. pylori infection by rapid urease test or histological evaluation of gastric antrum and corpus callosum samples by Giemsa staining Informed consent of the patient

Exclusion criteria:

Age

From **18 years** old

Gender

Both

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: **86**

Randomization (investigator's opinion)

Not randomized

Randomization description

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

Research Ethics Committee of Tabriz University of Medical Sciences

Street address

University Street

City

Tabriz

Province

East Azarbaijan

Postal code

5165665931

Approval date

2023-07-29, 1402/05/07

Ethics committee reference number

IR.TBZMED.REC.1402.374

Health conditions studied

1

Description of health condition studied

Helicobacter pylori [H. pylori]

ICD-10 code

B96.81

ICD-10 code description

Helicobacter pylori [H. pylori] as the cause of diseases classified elsewhere

Primary outcomes

1

Description

Eradication of H. pylori, evaluated by urine stool antigen test

Timepoint

8 weeks after the end of treatment

Method of measurement

urine stool antigen test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: A 14-day four-drug regimen containing rifaximin (rifaximin 500 mg, amoxicillin 1 g, Pantoprazole 40 mg and bismuth tablets, all twice a day)

Category

Treatment - Drugs

2

Description

Control group: Standard 14-day drug regimen (clarithromycin 500 mg, amoxicillin 1 g, pantoprazole 40 mg and bismuth tablets, all twice a day)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Seyed Yaghoob Moaddab

Street address

University Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Parviz Shahabi M.D.

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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

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Zahra Vaez Mousavi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The study results will be published as an article. The study protocol and statistical analysis used in the article will be considered.

When the data will become available and for how long

It will be published a year after the study is completed and will be available in the sources

To whom data/document is available

Information will be made available after permission of the university for academic researchers and institutions

Under which criteria data/document could be used

Other researchers can use the results of the study in their review and meta-analysis.

From where data/document is obtainable

Author: Seyede Zahra Vaez Mousavi

What processes are involved for a request to access data/document

Upon request, the corresponding author may respond

Comments