Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 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
City
Tabriz
Province
East Azarbaijan
Postal code

5166614756

Phone
+98 41 3334 7054

Email
vaezmousavi@tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Parviz Shahabi M.D.

Street address
Golgasht Street

City
Tabriz

Province
East Azarbaijan

Postal code
5166614756

Phone
+98 41 3334 7054

Email
shahabip@tbzmed.ac.ir

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

Street address
No. 200, Novin AVE., Ghatran Blvd., Tabriz

City
Tabriz

Province
East Azarbaijan

Postal code
5173645481

Phone
+98 41 3551 4025

Fax

Email
vaezmousavi@tbzmed.ac.ir

Person responsible for scientific 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

Street address
No. 200, Novin AVE., Ghatran Blvd., Tabriz

City
Tabriz

Province
East Azarbaijan

Postal code
5173645481

Phone
+98 41 3551 4025

Fax

Email
vaezmousavi@tbzmed.ac.ir

Person responsible for updating data

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

Street address
No. 200, Novin AVE., Ghatran Blvd., Tabriz

City
Tabriz

Province
East Azarbaijan

Postal code
5173645481

Phone
+98 41 3551 4025

Fax

Email

vaezmousavi@tbzmed.ac.ir

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