

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Assessment of dual drug therapy effect with coamoxiclav-based on *Helicobacter pylori* eradication

Protocol summary

Study aim

Determining the effect of coamoxiclav-based two-drug treatment on eradication of *Helicobacter pylori*

Design

The present study is a randomized clinical trial without blinding that will be performed in patients referred to Imam Khomeini Hospital in Urmia and will be randomly divided into two groups using Random allocation computer software.

Settings and conduct

Patients referred to Imam Khomeini Hospital in Urmia who have been diagnosed with *Helicobacter pylori* infection by a positive pathology or serological test will be included in the study. Patients in the treatment of side effects and drug tolerance by telephone follow-up and all cases are recorded. Two weeks after the end of treatment, the patient will have a urease breath test and if the test is positive, the respiratory test will be registered as a treatment failure and if the test is negative, it will be registered as a successful eradication of *Helicobacter pylori*.

Participants/Inclusion and exclusion criteria

Age over 18 years *Helicobacter pylori* serology test is positive Severe disorders affecting the gastrointestinal tract No malignancy of the gastrointestinal tract Non-pregnant and non-lactating No history of radiation therapy No allergies to any of the antibiotics used in the study No active gastrointestinal bleeding

Intervention groups

The two-drug regimen consists of amoxicillin 500 mg twice daily with coamoxiclav 625 mg twice daily and rabizol four times daily for two weeks, after that, antibiotics are discontinued and rabizol alone is administered for two weeks later. The standard regimen includes amoxicillin 1000 mg twice daily, bismuth twice daily, metronidazole 500 mg twice daily, and pantoprazole twice daily for two weeks. The drugs are then discontinued and pantoprazole is continued for two weeks.

Main outcome variables

Eradication of *Helicobacter pylori*

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201213049694N1**

Registration date: **2020-12-15, 1399/09/25**

Registration timing: **registered_while_recruiting**

Last update: **2020-12-15, 1399/09/25**

Update count: **0**

Registration date

2020-12-15, 1399/09/25

Registrant information

Name

Arezoo Delshad Sisi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3198 8002

Email address

arezoo.delshad@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-22, 1399/07/01

Expected recruitment end date

2021-02-18, 1399/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of dual drug therapy effect with coamoxiclav-based on Helicobacter pylori eradication

Public title

Effect of dual drug therapy with coamoxiclav-based on Helicobacter pylori eradication

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Helicobacter pylori serology test is positive Severe disorders affecting the gastrointestinal tract

Exclusion criteria:

Gastrointestinal malignancy Pregnant and lactating History of radiotherapy Allergy to any of the antibiotics used in the study Active gastrointestinal bleeding

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **188**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients randomly using computer software Random allocation into two groups of 94 patients treated with amoxicillin-based two-drug regimen coamoxiclav-based and quadruple regimen will be standard.

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 Urmia University of Medical Sciences

Street address

West Azarbaijan University of Medical Sciences and Health services, next to emergency department, Jahad St., Resalat Boulevard

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Approval date

2020-09-30, 1399/07/09

Ethics committee reference number

IR.UMSU.REC.1399.262

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 eradication

Timepoint

After 2weeks of completion of treatment

Method of measurement

Urea breath test

Secondary outcomes

1

Description

Drug Side effects

Timepoint

During and after the course of treatment

Method of measurement

Ask the patient

Intervention groups

1

Description

Intervention group: The two-drug regimen consists of amoxicillin 500 mg twice daily with coamoxiclav 625 mg twice daily and rabizol four times daily for two weeks, after that, antibiotics are discontinued and rabizol alone is administered for two weeks later

Category

Treatment - Drugs

2

Description

Control group: Control group: Standard regimen includes amoxicillin 1000 mg twice daily, bismuth twice daily, metronidazole 500 mg twice daily and pantoprazole twice daily for two weeks. The drugs are then discontinued and pantoprazole is continued for two weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Mohammad Reza Pashaei

Street address

Imam Khomeini Hospital, Ershad Street

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West Azarbaijan

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5715781351

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+98 44 3346 9931

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emam-h-urm@umsu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Iraj Mohebbi

Street address

West Azarbaijan University of Medical Sciences and Health services, next to emergency department, Jahad St., Resalat Boulevard

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Phone

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Email

mohebbi_iraj@yahoo.co.uk

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Oroumia 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

Oroumia University of Medical Sciences

Full name of responsible person

Mohammad Reza Pashaei

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

gastroenterology and hepatology

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Email

dr.pashaei@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Mohammad Reza Pashaei

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

gastroenterology and hepatology

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Person responsible for updating data

Contact

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Arezoo Delshad Sisi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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Email

arezoo.delshad@gmail.com

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

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All underlying information, grouping and the result of treatment of patients without mentioning the name of the patient in Excel and SPSS files are recorded and presented.

When the data will become available and for how long

6 months after the article to be published

To whom data/document is available

All academic and non-academic person

Under which criteria data/document could be used

In order to request the results and outputs of data analysis in the SPSS software, after submitting the application and approval of Urmia University of Medical Sciences, statistical outputs will be provided

From where data/document is obtainable

Vice chancellor for research and technology of Urmia University of Medical Sciences

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

After submitting the application and approval of the Deputy of research and Technology of Urmia University of Medical Sciences, the results will be sent during the maximum one month period by researcher.

Comments