

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of helicobacter pylori eradication rate with four different quadruple regimens in dyspeptic patients.

Protocol summary

Summary

Objectives: The aim of this study was to compare the eradication of Helicobacter pylori in dyspeptic patients is four quadruple regimen. Design and Methods: In this prospective, randomized, open-label study , 270 patients with positive rapid urease test were randomly divided into four treatment groups. Inclusion and exclusion criteria: Patients with positive rapid urease test that their chronic gastritis and Infection with Helicobacter pylori confirmed with histology were entered and Persons under 18 years of age at the time of endoscopy, those in the last month or bismuth compounds contain any antibiotics for any illness received., Pregnant and lactating women, people with serious diseases such as congestive heart failure, end-stage renal failure , cirrhosis and psychosis, patients with active gastrointestinal bleeding (upper), previous use of H. pylori eradication regimen and any favism patients were excluded from the study. Interventions: Group A: Treatment with omeprazole + amoxicillin + clarithromycin + bismuth subcitrate for two weeks (73 patients) Group B: Treatment with omeprazole + tetracycline + bismuth subcitrate + metronidazole for two weeks (46 patients Group C: Treatment with omeprazole + amoxicillin + furazolidone + bismuth subcitrate for two weeks (64 patients Group D: The first week: omeprazole + amoxycillin + bismuth subcitrate + Furazolidone then the second week: omeprazole + amoxicillin + bismuth subcitrate + metronidazole (87 patients). The main outcome variables: Six weeks after stopping treatment, eradication rate, acceptance rate, and side effects were determined in each group.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013010612024N1**

Registration date: **2013-02-13, 1391/11/25**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-02-13, 1391/11/25

Registrant information

Name

Shahnaz Naghashi

Name of organization / entity

Liver and Gastrointestinal Diseases Research Center of Tabriz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tabriz University of Medical Sciences

Expected recruitment start date

2009-09-23, 1388/07/01

Expected recruitment end date

2010-11-21, 1389/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of helicobacter pylori eradication rate with four different quadruple regimens in dyspeptic patients.

Public title

Comparison of helicobacter pylori eradication rate with four different quadruple regimens in dyspeptic patients.

Purpose

Treatment

Inclusion/Exclusion criteria

Patients with positive rapid urea's test that confirmed with histological finding of helicobacter pylori infection and chronic gastritis were entered in study. Persons under 18 years of age at the time of endoscopy; those in the last month or bismuth compounds contain any antibiotics for any illness received; Pregnant and lactating women; people with serious diseases such as congestive heart failure; end-stage renal failure; cirrhosis and psychosis; patients with active gastrointestinal bleeding (upper); previous use of H. pylori eradication regimen and any favism patients were excluded from the study.

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **270**

Randomization (investigator's opinion)

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**

Ethics Committee of Tabriz University of Medical Sciences

Street address

Medical Sciences Vice for research, Third floor, Central Building Number 2, Tabriz University of Medical Sciences, Gholghasht st, Tabriz

City

Tabriz

Postal code

5165118

Approval date

2008-07-21, 1387/04/31

Ethics committee reference number

5/4/5656

Health conditions studied**1****Description of health condition studied**

Infection with Helicobacter pylori

ICD-10 code

B98.0

ICD-10 code description

Helicobacter pylori [H.pylori] as the cause of diseases classified to other chapters

Primary outcomes**1****Description**

eradication of Helicobacter pylori

Timepoint

6 weeks after end of treatment

Method of measurement

UBT

Secondary outcomes**1****Description**

Side effects of treatment

Timepoint

At the time of treatment

Method of measurement

Questionnaire

Intervention groups**1****Description**

Group "A": who received omeprazole 20mg / BID+amoxicillin1g/BID +bismuth subcitrate240 mg/ BID +clarithromycin 500mg / BID for 2 weeks (73 patients)

Category

Treatment - Drugs

2**Description**

Group B: Treatment with omeprazole 20mg / BID + tetracycline 500 mg/ QID+ bismuth subcitrate 240 mg/BID + metronidazole 250 mg/ QID for two weeks (46 patients)

Category

Treatment - Drugs

3**Description**

Group C: Treatment with omeprazole 20mg / BID + amoxicillin 1g/ BID + furazolidone 200mg/BID + bismuth subcitrate 240 mg/ BID for two weeks (64 patients)

Category

Treatment - Drugs

4

Description

Group D: The first week : omeprazole 20mg / BID + amoxicillin 1g/ BID + bismuth subcitrate 240mg/BID + Furazolidone 200 mg/ BID then the second week: omeprazole 20mg / BID + amoxicillin 1g/ BID + bismuth subcitrate 240mg/BID+ metronidazole 250 mg/QID (87 patients).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital endoscopy

Full name of responsible person

Fattahi Ebrahim

Street address

Gastrointestinal and Liver Disease Research Center, Tabriz University of Medical Sciences, Imam Reza Hospital, Ghoghast avey , Tabriz

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tabriz University of Medical Sciences

Full name of responsible person

Mirinezhad Seyed Kazem

Street address

Medical Sciences Vice for research, Third floor, Central Building Number 2, University of Medical Sciences, Ghoghast street, Azadi street, Tabriz

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Tabriz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Liver and gastrointestinal diseases research center of Tabriz University of Medical Sciences

Full name of responsible person

Naghashi Shahnaz

Position

GP/Researcher

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty