Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 + amoxicillin1g/ 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 + amoxycillin 1g/ BID + bismuth subcitrate 240mg/BID + Furazolidone200 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,Ghlghast 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

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Medical Sciences Vice for research, Third floor, Central Building Number 2, University of Medical Sciences, Gholghast 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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Position

Internist,Professor, Department of Internal

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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