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

**Registrant information**
Name: Shahnaz Naghashi
Name of organization / entity: Liver and Gastrointestinal Diseases Research Center of Tabriz University of Medical Sciences
Country: Iran (Islamic Republic of)
Phone: +98 41 1336 7473
Email address: naghashish@tbzmed.ac.ir

**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
None

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 + amoxicillin 1g / BID + bismuth subcitrate 240 mg/ BID + clarithromycin 500 mg / 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 + amoxycillin 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, Ghilghast 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, Gholsht street, Azadi street, Tabriz
City
Tabriz

**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
Street address
Liver and gastrointestinal diseases research center, Imam Reza hospital, Ghilghasht st
City
Tabriz
Postal code
5166614756
Phone
+98 41 1336 7473
Fax
+98 33 67499
Email
naghashish@tbzmed.ac.ir
Web page address

**Person responsible for scientific inquiries**

**Contact**
Name of organization / entity
Liver and gastrointestinal diseases research center of Tabriz University of Medical Sciences
Full name of responsible person
Fattahi Ebrahim
Position
Internist, Professor, Department of Internal
Other areas of specialty/work
Street address
Liver and gastrointestinal diseases research center of Tabriz University of Medical Sciences, Imam Reza hospital, Ghilghasht st, Tabriz
City
Tabriz
Postal code
5166614756
Phone
+98 41 1336 7473
Fax
+98 33 67499
Email
eattahie@tbzmed.ac.ir
Web page address

**Person responsible for updating data**

**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
Liver and gastrointestinal diseases research center of Tabriz University of Medical Sciences, Imam Reza hospital, Gholghast st. Tabriz

Street address

City
Tabriz

Postal code
5166614756

Phone
+98 41 1336 7473

Fax
+98 33 67499

Email
naghashish@tbzmed.ac.ir shahnaznaghashymd@gmail.com

Web page address

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