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 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. 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
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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
- 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
- 51651118

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 240mg/ 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
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1
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Grant name

Person responsible for general inquiries

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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