Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Sequential Therapy versus Quadruple Therapy for H.pylori Eradication in Iran

Protocol summary

Summary

Aim: To compare the efficacy of quadruple and sequential therapy in eradication of Helicobacter pylori . Method: Three-hundred H. pylori positive patients will enroll into the study. These patients will randomly divided into two groups; group I (n=150) receive quadruple therapy (20 mg omp bid, 240 mg bismuth subcitrate bid, 1000 mg tetracycline bid and 500 mg metronidazole bid) for 14 days, group II (n=150) receive sequential therapy (20 mg omp bid, 1000 mg amoxicillin bid for 5 days, followe by 20 mg omp bid, 500mg metronidazole bid, 500mg clarithromycin for the other 5 days). Design: Follow up breath test by 14c urea breath test (UBT) will perform 4 weeks after completion of treatment. Eradication will define as negative results on UBT. Inclusion: Patients with dyspepsia, gastrointestinal bleeding, history of post prandial fullness and vomiting, undertake endoscopy.Two biopsies of the antrum and gastric body will perform. Those patients who have a positive rapid urease test or histological evidence for H. pylori in the gastric mucosa will enroll. Exclusion:Patients with severe co morbidity, such as cirrhosis, kidney failure, severe heart disease, pregnancy, lactation and evidence of malignancy, a previous history of eradication of H. pylori, a history of NSAID use, alcohol consumption and H2 blocker or PPI in the past two weeks or who have receive antibiotics and bismuth subcitrate in the last month will be excluded. Intervention: All patients will visit again one week and two weeks after the start of treatment for clinical assessment and to control how the drugs will use and to record the side effects of treatment. Patients according to medication compliance will divided into three groups; namely, good (uncomplicat and taking full course of treatment), average (despite complications, complete the treatment course) and poor (due to complication, the treatment will discontinue. Outcome:Eradication rate of helicobacter pylori will report on base intention to treat and Per-protocol analysis. side effect of drugs will report and compliance will be divided into three groups; good (uncomplicated and taking full course of treatment), average (despite complications, complete the treatment course) and poor (due to complication, the treatment will discontinued) .

General information

Acronym

To compare the efficacy of quadruple and sequential therapy in eradication of H.Pylori: in a

IRCT registration information

IRCT registration number: **IRCT201103183836N1**
Registration date: **2011-08-13, 1390/05/22**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2011-08-13, 1390/05/22

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Jundishapour Ahvaz Uuniversity of Medical Science

Expected recruitment start date

2011-12-02, 1390/09/11

Expected recruitment end date

2012-11-20, 1391/08/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Sequential Therapy versus Quadruple Therapy for H.pylori Eradication in Iran

Public title
Sequential Therapy versus Quadruple Therapy for H.pylori Eradication in Iran

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion: Patients older than 14 years of age with dyspepsia, gastrointestinal bleeding, history of post prandial fullness and vomiting, undertake endoscopy.Two biopsies of the antrum and gastric body will perform. Those patients who have a positive rapid urease test or histological evidence for H. pylori in the gastric mucosa will enroll. Exclusion:Patients with severe comorbidity, such as cirrhosis, kidney failure, severe heart disease, pregnancy, lactation and evidence of malignancy, a previous history of eradication of H. pylori, a history of NSAID use, alcohol consumption and H2 blocker or PPI in the past two weeks or who haVE receive antibiotics and bismuth subcitrate in the last month will be excluded.

Age
From **14 years** old to **60 years** old

Gender
Both

Phase
1-2

Groups that have been masked
No information

Sample size
Target sample size: **300**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Jundishapour Ahvaz University of Medical Science

Street address
Golstan highway

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Ahvaz

Postal code
61357-15794

Approval date
2011-06-20, 1390/03/30

Ethics committee reference number
8594

Health conditions studied

1

Description of health condition studied
Peptic ulcer

ICD-10 code
K25-K26

ICD-10 code description
Gastric ulcer -Duodenal ulcer - erosion (acute) of stomach -erosion (acute) of duodenum

2

Description of health condition studied
Gastritis

ICD-10 code
K29

ICD-10 code description
Chronic gastritis, unspecified , Acute (erosive) gastritis with haemorrhage

Primary outcomes

1

Description
Eeradication helicobacter pylori

Timepoint
Four weeks

Method of measurement
Urea breath test

Secondary outcomes

1

Description
Side effect

Timepoint
Three days

Method of measurement
Good, intermediate and poor assessed by physician

Intervention groups

1

Description
Group I (n=150) will receive quadruple therapy (20 mg omperazole bid, 240 mg bismuth subcitrate bid, 1000 mg tetracycline bid and 500 mg metronidazole bid) for 14 days
Category
Treatment - Drugs

2

Description
Group II (n=150) will receive sequential therapy (20 mg omp bid, 1000 mg amoxicillin bid for 5 days, follow by 20 mg omperazole bid, 500mg metronidazole bid, 500mg clarithromycin for the other 5 days)
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Jundishapour Ahvaz Uuniversity of Medical Science
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Sponsors / Funding sources

1

Sponsor
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Jundishapour Ahvaz Uuniversity of Medical Science
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

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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