Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Prospective Randomized Trial of Esomeprazole versus Lansoprazole and Omeprazole Based Triple Therapy for H. Pylori Eradication in an Iranian Population

Protocol summary

Summary

Background: Although triple therapy with one PPI and two antibiotics for one week has been introduced as the treatment of choice, quadruple therapy in Iran is the standard treatment due to the organism's high resistance to treatment. Objective: Comparison of three different PPIs; esomeprazole, lansoprazole and omeprazole with a longer duration (10 days) for eradication of H. pylori in the Iranian population Methods and Materials: patients with endoscopic evidence of peptic ulcer, non-ulcer dyspepsia, gastritis or acid reflux and confirm H. pylori, either by histology or a positive urea test will randomly divide into three groups; namely, group I receive omeprazole, clarithromycin and and amoxicillin (OCA); group II receive lansoprazole (LCA) and group III receive esomeprazole (NCA) instead of omeprazole. response to treatment will define as eradication of H. pylori confirm by negative C14 urea. Inclusion/exclusion criteria :Three hundred patients with confirm pylori infection by histology and urea test will enroll in the study.Exclusion criteria includ previous treatment of H. pylori infection, previous use of any antibiotics or bismuth subcitrate or any PPI or H2 blockers within four weeks prior to endoscopy, use of NSAIDs for more than four weeks, history of allergy to medications, previous history of any gastric surgery, underlying diseases such as cirrhosis or uremia and pregnancy. Outcome measure: Patients come to the clinic one week after completion of the treatment to be evaluate for any potential drug side effect and also to be check for their compliance. To evaluate the efficacy of H. pylori eradication therapy, patients were examine with C14 urea respiratory test 40 days after completion of the treatment course. A questionnaire will use for each patient including the patient's symptoms, endoscopic findings, H. pylori status by urea test, pathology report and medication side effect. Side effects will systematically record throughout the study and will assess using a checklist administer by a physician and describe as 1-None or only mild: mild discomfort which don't interfere with the patients' normal daily activities 2-Intermediate: discomfort or side effects which interfer with the patients' normal daily activities. 3-Severe: side effects requiring cessation of treatment. We use ITT analysis to compare eradication of H. pylori in all the patients in the three study groups without considering their compliance. In addition, we perform per-protocol analysis to compare the eradication for all the patients

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201204043836N4**
Registration date: **2012-06-07, 1391/03/18**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2012-06-07, 1391/03/18

Registrant information

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Recruitment status

Recruitment complete

Funding source
Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date
2012-04-01, 1391/01/13
Expected recruitment end date
2012-12-15, 1391/09/25
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Prospective Randomized Trial of Esomeprazole versus Lansoprazole and Omeprazole Based Triple Therapy for H. Pylori Eradication in an Iranian Population

Public title
Prospective Randomized Trial of Esomeprazole versus Lansoprazole and Omeprazole Based Triple Therapy for H. Pylori Eradication in an Iranian Population
Purpose
Treatment
Inclusion/Exclusion criteria
Patients with endoscopic evidence of peptic ulcer, non-ulcer dyspepsia, gastritis or acid reflux with confirmation H. Pylori, either by histology or a positive Urease test will enroll in the study. Exclusion criteria: previous treatment of H. Pylori infection; previous use of any antibiotics or bismuth subcitrate or any PPI or H2 blocker within four weeks prior to endoscopy; use of NSAIDs for more than four weeks; history of allergy to medications; previous history of any gastric surgery; underlying diseases such as cirrhosis or, uremia and pregnancy
Age
From **30 years** old to **60 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **300**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Triple blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ahvaz Jundishapur University of Medical Sciences Ethics Committee
Street address
University city, Golstan
City
Ahvaz
Postal code
61357-15794
Approval date
2011-12-26, 1390/10/05
Ethics committee reference number
107

Health conditions studied

1

Description of health condition studied
peptic ulcer-gastritis-non ulcer dyspepsia
ICD-10 code
k25-k26-k2
ICD-10 code description
Gastric ulcer-Duodenal ulcer-Gastritis, unspecified-Dyspepsia

Primary outcomes

1

Description
Eradication helicobacter pylori
Timepoint
4 weeks
Method of measurement
Urea breath test

Secondary outcomes

1

Description
Side effects will systematically record throughout the study and will assess using a checklist administered by a physician
Timepoint
During study
Method of measurement
1-None or only mild: mild discomfort which dont interfere with the patients' normal daily activities. 2-Intermediate: discomfort or side effects which interfered with the patients' normal daily activities. 3-Severe: side effects requiring cessation of treatment.

Intervention groups

1

Description
Group I: 100 patients receive Omperazole 20mg bid, Clarithromycin 500mg bid and Amoxicillin 1000mg bid.(OCA regimen)
Category
Treatment - Drugs

2

Description
Group II: 100 patients will recive Lansoprazole 30mg bid, Clarithromycin 500mg bid and Amoxicillin 1000mg bid.(LCA regimen)
Category
Treatment - Drugs

3

Description
Group III(NCA) : 100 patients will recive Esomeprazole (Nexium) 40mg bid, Clarithromycin 500mg bid and Amoxicillin 1 gram bid.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Jundishapour Ahvaz Uuniversity of Medical Science
Full name of responsible person
Abdolrahim Masjedizadeh
Street address
Azadgan street.departemant gatroenterology.Imam hospita
City
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Jundishapour Ahvaz Uuniversity of Medical Science
Full name of responsible person
Dr Faghei
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University City ,Golstan street
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Ahvaz
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

Contact
Name of organization / entity
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Full name of responsible person
Abdolrahim Masjedizadeh
Position
Associate professor
Other areas of specialty/work
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Person responsible for updating data

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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