

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jun 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 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 interfere 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

##### Name

Abdolrahim Masjedi Zadeh

##### Name of organization / entity

Jundishapour Ahvaz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 1337 6922

##### Email address

rmasjedi@ajums.ac.ir

##### 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 receive Lansoprazole 30mg bid, Clarithromycin 500mg bid and Amoxicillin 1000mg bid.(LCA regimen)

#### Category

Treatment - Drugs

### 3

#### Description

Group III(NCA) : 100 patients will receive 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 gastroenterology.Imam hospita

##### City

Ahvaz

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Jundishapour Ahvaz Uuniversity of Medical Science

##### Full name of responsible person

Dr Faghei

##### Street address

University City ,Golstan street

##### City

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

Imam Hospital

##### Full name of responsible person

Abdolrahim Masjedizadeh

##### Position

Associate professor

##### Other areas of specialty/work

##### Street address

Gastroentology Ward --Imam hospital-Azadgan Street

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masjedi-r@ajums.ac.ir

##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Imam Hospital

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Eskandar Hajiani

##### Position

Associate professor

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## Person responsible for updating data

### Contact

**Name of organization / entity**

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**Full name of responsible person**

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**Position**

Associate professor

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**Fax**

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**Email**

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**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*