

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

A clinical trial to comparing the efficacy of Levofloxacin versus Clarithromycin on eradication of Helicobacter Pylori infection

Protocol summary

Summary

Goal of study: goal of this study is to evaluate Levofloxacin based versus Clarithromycin based regimens, efficacy in eradication of Helicobacter Pylori (HP) infection. Designing of study: single center randomized, clinical trial. Inclusion criteria to this study: all patients undergoing upper endoscopic procedure with positive rapid urease test (RUT). Exclusion criteria from this study: pregnancy; Previous consumption proton pump inhibitors (PPI) or Bismuth in the preceding one month; Gastrointestinal (GI) bleeding; consumption of alcohol or substance; advanced chronic diseases; lack of willingness to continue the treatment; suffering from any disease needing to consume another antibiotic or non-steroidal anti-inflammatory drugs (NSAIDs). Sample size: 120 patients. Methods & Intervention: patients with upper gastrointestinal symptoms who need endoscopic procedure and their RUT are positive for HP are entered into this study, divided into 2 groups. First group (A) will be treated by Levofloxacin (500mg daily) plus Amoxicillin (1 gr twice a day) plus Omeprazole (20 mg daily) for 2 weeks. Second group (B) will be treated by Clarithromycin (500mg twice a day) plus Amoxicillin (1 gr twice a day) plus Omeprazole (20 mg daily) for 2 weeks. After complementary the main course of treatment they will receive maintenance 4 weeks with omeprazole. After two weeks of not taking any medicine mentioned before every patient will be tested by stool antigen. Ultimately eradication rate of HP will be compared in two groups. Intervention time: 2 weeks Primary outcome: Compare eradication of HP infection by stool antigen of HP between 2 groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015081818124N2**

Registration date: **2015-12-23, 1394/10/02**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-12-23, 1394/10/02

Registrant information

Name

Ali Akbar Hajiaghamohammadi

Name of organization / entity

Metabolic Diseases Research Center, Qazvin
University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Qazvin University of Medical Sciences

Expected recruitment start date

2015-02-20, 1393/12/01

Expected recruitment end date

2015-11-22, 1394/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial to comparing the efficacy of Levofloxacin versus Clarithromycin on eradication of Helicobacter Pylori infection

Public title

Levofloxacin effect on eradication of Helicobacter Pylori infection

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria to this study: all patients undergoing upper endoscopic procedure with positive rapid urease test (RUT). Exclusion criteria from this study: pregnancy; Previous consumption proton pump inhibitors (PPI) or Bismuth in the preceding one month; Gastrointestinal (GI) bleeding or any complication of peptic ulcer disease (PUD); consumption of alcohol or substance; advanced chronic disease: Diabetes mellitus, Hypertension, Cirrhosis, Cerebrovascular attack, Renal insufficiency, Coronary artery disease and gastric cancer; lack of willingness to continue the treatment; lack of willingness to complete the period of treatment; suffering from any disease needing to consume another antibiotic or non-steroidal anti-inflammatory drugs (NSAIDs).

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **120**

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**

Qazvin University of Medical Sciences

Street address

Qazvin University of Medical Sciences, Bahonar Blvd,
Qazvin

City

Qazvin

Postal code**Approval date**

2015-02-04, 1393/11/15

Ethics committee reference number

9943

Health conditions studied**1****Description of health condition studied**

Helicobacter Pylori infection

ICD-10 code

B98.0

ICD-10 code description

Helicobacter pylori

Primary outcomes**1****Description**

Eradication of Helicobacter Pylori infection

Timepoint

Two months after beginning of treatment

Method of measurement

Primary evaluation of Helicobacter Pylori infection is based on rapid urease test and then eradication will be assessed by Helicobacter Pylori stool antigen

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group will take 20 mg of Omeprazole capsule once daily, 1000 mg Amoxicillin capsule two times a day and 500 mg tablet of Levofloxacin once daily. Then Omeprazole will be continued for another 4 weeks.

Category

Treatment - Drugs

2**Description**

Control group will take 20 mg Omeprazole Capsule once daily, 1000 mg capsule of Amoxicillin and Clarithromycin 500 mg capsule two times a day. Then Omeprazole will be continued for another 4 weeks.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Velayat hospital, Qazvin

Full name of responsible person

Dr. Ali Akbar Haj Agha Mohammadi

Street address

Velayat hospital, Taavon Sq, Minoodar, Qazvin

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Qazvin University of Medical Sciences

Full name of responsible person

Dr. Ali Akbar Haj Agha Mohammadi

Street address

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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

Qazvin University of Medical Sciences

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**

Qazvin University of Medical Sciences

Full name of responsible person

Dr. Ali Akbar Haj Agha Mohammadi

Position

Associated professor, Gastroenterologist

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Web page address**Person responsible for scientific****inquiries****Contact****Name of organization / entity**

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Full name of responsible person

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Web page address**Person responsible for updating data****Contact****Name of organization / entity**

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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