

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Comparison of the efficacy of Levofloxacin and Clarithromycin in quadruple therapy for the eradication of *Helicobacter pylori*

Protocol summary

Study aim

Comparison of the efficacy of Levofloxacin and Clarithromycin in quadruple therapy for the eradication of *Helicobacter pylori*

Design

In this study, 210 patients with peptic ulcer and proven *Helicobacter pylori* infection referred to the Alzahra Gastrointestinal Hospital will be included in the study and will be randomly assigned to two groups of intervention and control and each participant will be assigned a code.

Settings and conduct

This study is a randomized clinical trial. Adults with peptic ulcer and proven *Helicobacter pylori* infection referred to the Alzahra Gastrointestinal Hospital will be included in the study and will be randomly assigned to two groups. The first group is treated with Clarithromycin 500 mg twice daily, Amoxicillin 1 g twice daily, Bismuth 525 mg twice daily, and Pantazole 40 mg twice daily for two weeks. The second group of patients will take levofloxacin 500 mg daily for two weeks instead of clarithromycin. To determine the success of eradication, a stool antigen test will be used at least 4 weeks after the end of the treatment. To assess the severity of symptoms, a short form of the Leeds Dyspepsia Questionnaire at the beginning of the study and the eradication evaluation (4 weeks after the completion of the treatment) will be completed through the interview. To measure the side effects, a standard questionnaire will be completed at the end of the course (day 15) and then at the time of the eradication evaluation (4 weeks after treatment) through the interview. Patient tolerance is measured with five good options, mild intolerance, moderate intolerance, severe intolerance, and forced discontinuation of medication through an interview at the end of the treatment period (day 15). Finally, data analysis is done through SPSS v.16 and Chi-Square, Independent Sample T-Test and MC Nemar tests in both Intention to Treat and Per-Protocol methods.

Participants/Inclusion and exclusion criteria

People over 18 years of age with *Helicobacter pylori* infection proven without previous history of severe illness, surgery and previous *Helicobacter pylori* infection

Intervention groups

The control group consisted of patients treated with Clarithromycin based on four regimens and the intervention group included patients treated with four drugs based on levofloxacin.

Main outcome variables

Eradication of *Helicobacter Pylori* infection Separated drug effects Dyspepsia severity Patient tolerance

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171223038001N1**

Registration date: **2018-01-05, 1396/10/15**

Registration timing: **registered_while_recruiting**

Last update: **2018-01-05, 1396/10/15**

Update count: **0**

Registration date

2018-01-05, 1396/10/15

Registrant information

Name

Reyhane Hosseini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3230 4933

Email address

reyhane_001@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-26, 1396/10/05

Expected recruitment end date

2018-12-26, 1397/10/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy of Levofloxacin and Clarithromycin in quadruple therapy for the eradication of Helicobacter pylori

Public title

Eraddication of Helicobacter pylori for quadruple therapy with base of Clarithromycin compared with Levofloxacin

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Aged 18 years and older Patients with dyspepsia and upper digestive tract symptoms Peptic Ulcers in Upper Gastrointestinal Endoscopy Helicobacter pylori infection in rapid test of urease The desire to participate in the study Lack of severe illness Not having a history of upper gastrointestinal surgery Not taking antibiotics, PPIs and NSAIDs in the last three months Not having eradication history of Helicobacter pylori Absence of ContraIndications for the Consumption of quadruple therapy

Exclusion criteria:

Low drug intake (for any reason) Incidence of severe drug complications during the study

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **210**

Actual sample size reached: **133**

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling is consecutive. Patients who referred to the gastroenterologist for upper gastrointestinal symptoms and who have had ulcerative peptic ulcer endoscopy and who have been diagnosed with Helicobacter Pylori infection according to a quick test of urease, according to other criteria for entry and absence of study Then, after explaining how the plan is implemented and receiving written consent, patients are randomly assigned (using a random number table generated by Random Allocation Software) into two groups.

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 Isfahan University of Medical Sciences

Street address

Jey Ave, opposite Sarvestan, Haft Tir Alley, Afshin deadlock, 56 No

City

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Province

Isfahan

Postal code

8156884541

Approval date

2017-02-01, 1395/11/13

Ethics committee reference number

ir.mui.rec.1396.3.010

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

Helicobacter pylori infection

ICD-10 code

B96.81

ICD-10 code description

Helicobacter pylor

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

Eradication of Helicobacter pylori infection

Timepoint

Stool antigen Helicobacter pylori test 4 weeks after discontinuation of treatment

Method of measurement

Stool antigen Helicobacter pylori test

Secondary outcomes**1****Description**

Dyspepsia severity
Timepoint
Before treatment and 4 weeks after treatment
Method of measurement
questionnaire

Intervention groups

1

Description
Intervention group: Patients with Helicobacter Pylori infection receiving four regimens based on levofloxacin 500 mg once daily for 14 days.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra Hospital Gastrointestinal clinic
Full name of responsible person
reyhane hosseini
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
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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
Esfahan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Esfahan University of Medical Sciences
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reyhane hosseini
Position
Internal resident of medicine
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Person responsible for updating data

Contact

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reyhane hosseini
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Street address
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deadlock, 56 No
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available