Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 Pentazole 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
Isfahan
Province
Isfehan
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

Street address

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reyhane_001@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

vahid sebghatollahi

Street address

Sofah Blvd, Alzahra Hospital

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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

Full name of responsible person

reyhane hosseini

Position

Internal resident of medicine

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

وحید سبقت اللهی

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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Person responsible for updating data

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
reyhane hosseini
Position
Internal resident of medicine
Latest degree
Medical doctor
Other areas of specialty/work
Internal Medicine
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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