Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of levofloxacin versus clarithromycin efficacy in bismuth-containing quadruple therapy for helicobacter pylori eradication

Protocol summary

Study aim
Determination of Helicobacter Remedy in the 4-Day Medicinal Product containing levofloxacin in patients with dyspepsia

Design
Clinical trials in the 4th drug regimen

Settings and conduct
Patients referred to the gastroenterology clinic and internal wards of the Shahid Beheshti Hospital of Kashan in the year 1339-98, who have been diagnosed with Helicobacter Pylori infection following gastroscopy and biopsy or fecal antigen test. It should be noted that the patients were given the necessary explanations regarding the observance of food safety and the correct and regular administration of medications. At the end of the first and second weeks of treatment, patients were registered for the correct use of drugs and adverse drug reactions, and all cases were recorded in the questionnaire. After the end of the antibiotic treatment period, treatment with omeprazole is continued for another 4 weeks and 4 weeks after discontinuation of omeprazole, a fecal antigen test is performed for both groups to confirm the eradication of the infection.

Participants/Inclusion and exclusion criteria
Patients referred to the gastroenterology clinic and internal wards of the Shahid Beheshti Hospital of Kashan in the year 1339-98, who have been diagnosed with Helicobacter Pylori infection following gastroscopy and biopsy or fecal antigen test.

Intervention groups
Eradication rate of Helicobacter in a 4-drug regimen containing levofloxacin in treated patients Eradication rate of Helicobacter in Clarithromycin-containing drug regimen in patients undergoing treatment The rate of eradication of Helicobacter in the 4-drug regimen of levofloxacin is different from that of Clarithromycin in dyspeptic patients. The incidence of common adverse drug reactions in patients treated with levofloxacin

Main outcome variables
Eradication of Helicobacter with Medication

General information

Reason for update
A typo is incorrect in entering the sample size and in contrast to the experimental number

Acronym

IRCT registration information
IRCT registration number: **IRCT20190606043826N1**
Registration date: **2019-06-24, 1398/04/03**
Registration timing: **retrospective**

Last update: **2019-12-26, 1398/10/05**
Update count: **1**

Registration date
2019-06-24, 1398/04/03

Registrant information

Name
Marzieh Mollaei Ardestani

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 5558 0931

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mollaei-m@kaums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-06-05, 1398/03/15

Expected recruitment end date
2019-06-20, 1398/03/30

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of levofloxacin versus clarithromycin efficacy in bismuth-containing quadruple therapy for helicobacter pylori eradication

Public title

Comparison of levofloxacin versus clarithromycin efficacytherapy for helicobacter pylori eradication

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Positive h.pylori people have indications of treatment Age between 14 and 70 years Patients with informed consent to participate in the study

Exclusion criteria:

Do not use the correct and regular drug Incidence of unbearable side effects Pregnancy and lactation The presence of chronic liver, kidney and gastrointestinal diseases simultaneously Previous history of h.pylori treatment in a recent month

Age

From **14 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **194**

Randomization (investigator's opinion)

N/A

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

Faculty of Medicine and Dentistry- Kashan University of Medical Sciences

Street address

Kashan University of Medical Sciences

City

Kashan

Province

Isfehan

Postal code

8711111111

Approval date

2018-05-27, 1397/03/06

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1397.017

Health conditions studied

1

Description of health condition studied

Helicobacter pylori

ICD-10 code

B98.0

ICD-10 code description

Helicobacter pylori [H.pylori] as the cause of diseases classified to other chapters

Primary outcomes

1

Description

The presence or absence of stool antigen,

Timepoint

At the end of the first and second weeks of treatment

Method of measurement

Fecal antigen test to confirm eradication of infection

2

Description

Incidence or absence of drug side effects

Timepoint

At the end of the first and second weeks of treatment

Method of measurement

questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group was as follows treated with 4 doses of bismuth substrate (2 tablets every 12 hours), omeprazole (20 mg every 12 hours),amoxicillin (1 g every 12 hours) Clarithromycin (500 mg every 12 hours)

Category

Treatment - Drugs

2

Description

The intervention group : treated with 4 drugs including

bismuth subcetate (2 tablets every 6 hours), omeprazole (20 mg every 12 hours), amoxicillin (1 g every 12 hours) Levofloxacin (500 mg every 12 hours)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital of Kashan

Full name of responsible person

Abbas Arj

Street address

Kashan university of medical sciences, Qotbe Ravandi Blvd, Kashan

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Email

mollaei-m@Kaums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Seyed Alireza Moraveji

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

Kashan 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

Kashan University of Medical Sciences

Full name of responsible person

Abbas Arj

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Abbas Arj

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity
Kashan University of Medical Sciences

Full name of responsible person
Abbas Arj

Position
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Email
Dr_Arj@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

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

Data Dictionary
Not applicable

Title and more details about the data/document
Part of the data relating to the Helicobacter counts can be shared.

When the data will become available and for how long
After analyzing the results, the data access period is free.

To whom data/document is available
Academic Institutions and Researchers

Under which criteria data/document could be used
For use in future studies.

From where data/document is obtainable
Corresponding Author

What processes are involved for a request to access data/document
Send an email to the author and get the information

Comments