

# 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

##### Email address

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

Isfahan

#### 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

**City**

Kashan

**Province**

Isfahan

**Postal code**

8711111111

**Phone**

+98 31 5550 0111

**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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Kashan

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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

**Street address**

Kashan university of medical sciences, Qotbe Ravandi Blvd, Kashan

**City**

Kashan

**Province**

Isfahan

**Postal code**

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**Phone**

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**Email**

Dr\_Arj@yahoo.com

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

Kashan University of Medical Sciences

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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

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**Phone**

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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**