

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

Comparison of triple treatment regimen containing levofloxacin with triple treatment regimen containing clarithromycin in the first line of treatment of patients with Helicobacter pylori infection referred to the clinic of Imam Khomeini Hospital during 2021-2022.

Protocol summary

Study aim

The main objectives of the project: Comparison of triple treatment regimen containing levofloxacin with triple treatment regimen containing clarithromycin in the first line of treatment of patients with Helicobacter pylori infection

Design

Clinical trial with control group, with parallel groups, without blinding, randomized, phase 3 on 130 patients. A table of four blocks was used for randomization.

Settings and conduct

Gastroenterology Clinic of Imam Khomeini Hospital

Participants/Inclusion and exclusion criteria

Confirmation of the presence of H.pylori by fecal antigen test

Intervention groups

Group 1: Triple treatment regimen containing levofloxacin in Helicobacter pylori eradication Group 2: Triple treatment regimen containing clarithromycin in eradication of Helicobacter pylori

Main outcome variables

Helicobacter pylori eradication rate, adherence rate, treatment complications

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210209050313N1**

Registration date: **2021-05-20, 1400/02/30**

Registration timing: **prospective**

Last update: **2021-05-20, 1400/02/30**

Update count: **0**

Registration date

2021-05-20, 1400/02/30

Registrant information

Name

Mohamad Seraj Nasiri Toosi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-23, 1400/05/01

Expected recruitment end date

2022-03-21, 1401/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of triple treatment regimen containing levofloxacin with triple treatment regimen containing clarithromycin in the first line of treatment of patients with Helicobacter pylori infection referred to the clinic of Imam Khomeini Hospital during 2021-2022.

Public title

Comparison of two antibiotic regimens in eradicating Helicobacter pylori

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Confirmation of the presence of H.pylori by fecal antigen test

Exclusion criteria:

History of previous treatment for eradication of Helicobacter pylori Age less than 18 years and over 65 years History of allergy or severe reaction to drugs used in the plan History of major surgery on the gastrointestinal tract such as bilirut and bypass and gastrogenostomy And gastrectomy Severe underlying disease such as liver failure) Cirrhosis of the liver (or kidney) Creatinine above 2 (or proven malignancy Untreated active Active pregnancy or lactation Inability to follow up Use of proton pump inhibitors And antibiotics in the last 4 weeks Contraindications to the use of prescription drugs

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **130**

Randomization (investigator's opinion)

Randomized

Randomization description

According to the list, he receives one of two antibiotic regimens. The random list in the clinic is numbered from 1 to 130. In front of each number, one of the antibiotic regimens is written and the patients receive the intervention group or the control group according to the list of one of the two regimens. The list consists of four blocks, in each block, there are two intervention groups and two control groups that are randomly arranged inside the block. The blocks themselves were also randomly placed in the list. Random allocation at each stage is done by the methodologist.

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 Tehran University of Medical Sciences

Street address

Gastroenterology Department.; Imam Khomeini Hospital Complex. Dr. Gharib Street, Keshavarz Boulevard. tehran

City

Tehran

Province

Tehran

Postal code

۱۴۱۹۷۳۳۱۴۱

Approval date

2021-04-19, 1400/01/30

Ethics committee reference number

IR.TUMS.IKHC.REC.1400.041

Health conditions studied

1

Description of health condition studied

Helicobacter pylori infection

ICD-10 code

B96.81

ICD-10 code description

Helicobacter pylori [H. pylori] as the cause of diseases classified elsewhere

Primary outcomes

1

Description

Negative stool antigen test for Helicobacter pylori infection at the end of treatment

Timepoint

2 months and 10 days after starting treatment

Method of measurement

Stool antigen test for Helicobacter pylori infection

Secondary outcomes

1

Description

Adherence to treatment

Timepoint

11 days after starting treatment

Method of measurement

questionnaire

2

Description

Complications of treatment

Timepoint

11 days after starting treatment

Method of measurement

questionnaire

Intervention groups

1

Description

Intervention group: Levofloxacin 500 mg daily, amoxicillin 1 g twice daily and omeprazole 20 mg twice daily for 10 days, then omeprazole 20 mg daily for 4 weeks

Category

Treatment - Drugs

2

Description

Control group: clarithromycin 500 mg, amoxicillin 1 g and omeprazole 20 mg all twice a day for 10 days then 4 weeks daily omeprazole 20 mg

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital Complex

Full name of responsible person

Mohamad Taher

Street address

Gastroenterology Department.; Imam Khomeini Hospital Complex. Dr. Gharib Street, Keshavarz Boulevard. Tehran

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Email

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohamad Ali Sahraian

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Mohamad Taher

Position

Associate Professor

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

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Other areas of specialty/work

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Person responsible for updating data

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Position

Student

Latest degree

Medical doctor

Other areas of specialty/work

Others

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not 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