Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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
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Gastroenterology Department،; Imam Khomeini Hospital Complex، Dr. Gharib Street، Keshavarz Boulevard، Tehran
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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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msahrai@tums.ac.ir
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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Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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Person responsible for updating data

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Position

Student

Latest degree

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Other areas of specialty/work

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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