Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparing the effectiveness of the four-drug regimen containing levofloxacin with the effectiveness of the four-drug regimen containing metronidazole in the treatment of Helicobacter pylori eradication

Protocol summary

Study aim
Comparing the efficacy of levofloxacin and metronidazole regimens in the quadruple treatment of Helicobacter pylori eradication

Design
A clinical trial with a control group with parallel groups, randomized with blocks, one-sided blind, randomized phase 3 on 162 patients.

Settings and conduct
In this single-blind clinical trial, patients referred to the Gastroenterology Clinic of Taleghani Hospital, Tehran, suffering from Helicobacter pylori are admitted. Division of groups will be 1:1 with parallel arms and using random blocks (block size four). The first group will receive the quadruple treatment of omeprazole, bismuth, amoxicillin and levofloxacin and the second group will receive the quadruple treatment of omeprazole, bismuth, amoxicillin and metronidazole. The duration of treatment is 14 days. Before and after the intervention, patients are evaluated for Helicobacter pylori infection with stool antigen test. Patients will be referred to evaluate the root of Helicobacter pylori two weeks after the end of the treatment.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Helicobacter pylori-positive patients. Exclusion criteria: previous allergic reaction to antibiotics (amoxicillin, clarithromycin, tinidazole), patients taking probiotics and proton pump inhibitors (esomeprazole), occurrence of side effects due to simultaneous use of four drugs and the need to stop taking one of medications, pregnancy

Intervention groups
The first group will receive the quadruple treatment of omeprazole, bismuth, amoxicillin and levofloxacin and the second group will receive the quadruple treatment of omeprazole, bismuth, amoxicillin and metronidazole.

Main outcome variables
Eradication of Helicobacter pylori, occurrence of drug side effects

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240311061259N1**
Registration date: **2024-10-10, 1403/07/19**
Registration timing: **registered_while_recruiting**

Last update: **2024-10-10, 1403/07/19**
Update count: **0**

Registration date
2024-10-10, 1403/07/19

Registrant information

Name
Amir Sadeghi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 2243 2526

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amirsadeghimd@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-10-06, 1403/07/15

Expected recruitment end date
2025-01-19, 1403/10/30

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effectiveness of the four-drug regimen containing levofloxacin with the effectiveness of the four-drug regimen containing metronidazole in the treatment of Helicobacter pylori eradication

Public title

Comparing the effect of levofloxacin with metronidazole in the eradication of Helicobacter pylori

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

positive helicobacter pylori

Exclusion criteria:

History of previous eradication therapy for Helicobacter pylori History of gastrectomy Stomach malignancy (including adenocarcinoma and lymphoma) Use of antibiotics (amoxicillin, clarithromycin, tinidazole) in the last four weeks

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **162**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are assigned to two groups using the random block method. The number of blocks will be 22 and in each block, two, four or six patients will be included in the study order. Random allocation of blocks of patients to two intervention groups will be done through Sealed Envelope online software. By referring to https://www.sealedenvelope.com/simple-randomiser/v1/lists by specifying the total number of samples, the number of possible samples in each randomized block (2, 4 and 6 patients) randomization by online software is done For example, like the following output: block identifier block size sequence within block treatment 1 2 1 Group B 1 2 2 Group A 2 4 1 Group A 2 4 2 Group B 2 4 3 Group B 2 4 4 Group A 3 2 1 Group A 3 2 2 Group B ... which is the block number, the number of patients in the block, and the random assignment of each patient (with the corresponding number) to the treatment group. The randomized list of blocks will be placed in sealed envelopes and will be provided to the gastroenterologist on a daily basis.

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 in Biomedical Research, Gastroenterology and Liver Research Institute, Shahid Behes

Street address

Arabi street, Velenjak

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2024-08-20, 1403/05/30

Ethics committee reference number

IR.SBMU.MSP.REC.1403.286

Health conditions studied

1

Description of health condition studied

Helicobacter pylori

ICD-10 code

B96.81

ICD-10 code description

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

Primary outcomes

1

Description

Helicobacter pylori eradication

Timepoint

Before the intervention and 14 days after the intervention

Method of measurement

stool antigen test

Secondary outcomes

1

Description

side effect of drugs

Timepoint

During the intervention and after the completion of the intervention

Method of measurement

History and clinical examination

Intervention groups

1

Description

Intervention group: Receiving quadruple therapy of omeprazole, bismuth, amoxicillin and levofloxacin

Category

Treatment - Drugs

2

Description

Intervention group: receiving quadruple therapy of omeprazole, bismuth, amoxicillin and metronidazole

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Gastroenterology and Liver Clinic of Taleghani Hospital

Full name of responsible person

Mohammad Javad Ehsani Ardakani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

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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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mahshid Malekian

Position

rezident

Latest degree

Specialist

Other areas of specialty/work

Internal Medicine

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Person responsible for updating data

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
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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
Protecting patients' privacy and confidentiality
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
No - There is not 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
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
Only the information related to the study protocol, the statistical analysis plan and the clinical study report will be made available to the requestors (and not publicly) to other researchers for guidance for further studies.
When the data will become available and for how long
After the publication of the article
To whom data/document is available
Researchers, students and professors in the field of gastroenterology
Under which criteria data/document could be used
For use in further research and if the source is cited
From where data/document is obtainable
corresponding author Dr Amir Sdaeghi amirsadeghimd@yahoo.com
What processes are involved for a request to access data/document
Send a request via email to the responsible author and mention the reason for the request and how to use the tens
Comments