Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of 5-day and 10-day levofloxacin based triple regimen to eradication of helicobacter pylori: An open-label randomized clinical trial

Protocol summary

Study aim

Comparison of Helicobacter pylori Eradication Rates Between 5-Day and 10-Day Levofloxacin-Based Triple Therapy Regimens

Design

A phase 3, randomized, controlled, parallel-group clinical trial conducted on 120 patients with Helicobacter pylori infection confirmed by biopsy. The Excel RAND function was used for randomization.

Settings and conduct

Study Setting: Ayatollah Rohani Hospital, Babol Methodology: Patients with confirmed H. pylori infection (via gastric biopsy) were randomly assigned to treatment groups.

Participants/Inclusion and exclusion criteria

The inclusion criteria for this study consist of all individuals between 18 and 60 years of age with a histologically confirmed Helicobacter pylori infection who voluntarily consent to participate. The exclusion criteria : a history of prior H. pylori eradication therapy; severe or chronic diseases; pregnant women; recent use (within the past month) of NSAIDs, antibiotics, or proton pump inhibitors; previous gastric surgery; severe renal impairment (creatinine >2 mg/dL); significant hepatic dysfunction; gastric cancer; and hypersensitivity to any of the study medications (levofloxacin, amoxicillin, or pantoprazole).

Intervention groups

The 5-day treatment group received amoxicillin 1 g twice daily, levofloxacin 500 mg (Tavanex®, Abidi Pharma) once daily and pantoprazole 40 mg (Abidi Pharma) twice daily for 5 days The 10-day treatment group received amoxicillin 1 g twice daily, levofloxacin 500 mg (Tavanex®, Abidi Pharma) once daily and pantoprazole 40 mg (Abidi Pharma) twice daily for 10 days

Main outcome variables

H. pylori eradication rate, treatment-related adverse events, patient compliance rates.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250426065481N1**
Registration date: **2025-05-27, 1404/03/06**
Registration timing: **registered_while_recruiting**

Last update: **2025-05-27, 1404/03/06**
Update count: **0**

Registration date

2025-05-27, 1404/03/06

Registrant information

Name
Amin Vahedi
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 11 4324 0633
Email address
dr.aminvahedi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-05-20, 1404/02/30

Expected recruitment end date

2025-07-23, 1404/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of 5-day and 10-day levofloxacin based triple regimen to eradication of helicobacter pylori: An open-label randomized clinical trial

Public title
Comparison of 5-day and 10-day levofloxacin based triple regimen to eradication of helicobacter pylori: An open-label randomized clinical trial
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All individuals aged 18 to 60 with a histologically confirmed Helicobacter pylori infection The patient's consent to participate in the study
Exclusion criteria:
Prior treatment for H. pylori eradication Severe and chronic medical conditions Pregnant women History of NSAID, antibiotic, or PPI use within the last 30 days Prior stomach surgery Severe kidney dysfunction [serum creatinine >2 mg/dL] Severe liver dysfunction Known hypersensitivity to levofloxacin, amoxicillin, or pantoprazole Gastric cancer
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization Type: Simple randomization- Individual-level randomization Randomization Tool: Participants are randomly assigned to groups using a computer-generated randomization code. Allocation is performed automatically without stratification or blocking. patients are assigned to either 5-day or 10-day treatment groups based on the pre-generated randomization code.
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
Research ethics committees of health research institute- Babol university of medical sciences
Street address
Endoscopy ward, Ayatollah Rohani hospital, Ganj afrooz Ave
City
Babol
Province
Mazandaran
Postal code
4614863313
Approval date
2024-11-10, 1403/08/20
Ethics committee reference number
IR.MUBABOL.HRI.REC.1403.185

Health conditions studied

1

Description of health condition studied
Helicobacter pylori infection
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
Helicobacter Pylori infection eradication
Timepoint
Five weeks after completing treatment (two weeks after stopping pantoprazole)
Method of measurement
Helicobacter pylori stool antigen test

Secondary outcomes

1

Description
Adverse effect- Constipation
Timepoint
Before starting the study, 5 days after starting treatment, and at the end of treatment
Method of measurement
Ask the patient in person or by phone

2

Description
Adverse effect- Diarrhea
Timepoint
Before starting the study, 5 days after starting treatment, and at the end of treatment
Method of measurement
Ask the patient in person or by phone

3

Description
Adverse effect- Nausea
Timepoint
Before starting the study, 5 days after starting treatment, and at the end of treatment
Method of measurement
Ask the patient in person or by phone

4

Description
Adverse effect- Vomiting
Timepoint
Before starting the study, 5 days after starting treatment, and at the end of treatment
Method of measurement
Ask the patient in person or by phone

5

Description
Adverse effect- Abdominal pain
Timepoint
Before starting the study, 5 days after starting treatment, and at the end of treatment
Method of measurement
Ask the patient in person or by phone

6

Description
Adverse effect- Heartburn
Timepoint
Before starting the study, 5 days after starting treatment, and at the end of treatment
Method of measurement
Ask the patient in person or by phone

7

Description
Adverse effect- Metallic taste
Timepoint
Before starting the study, 5 days after starting treatment, and at the end of treatment
Method of measurement
Ask the patient in person or by phone

8

Description
Adverse effect- Flatulence
Timepoint
Before starting the study, 5 days after starting treatment, and at the end of treatment
Method of measurement
Ask the patient in person or by phone

9

Description
adverse effect- Dizziness
Timepoint
Before starting the study, 5 days after starting treatment, and at the end of treatment
Method of measurement
Ask the patient in person or by phone

10

Description
Adverse effect- Low appetite
Timepoint
Before starting the study, 5 days after starting treatment, and at the end of treatment
Method of measurement
Ask the patient in person or by phone

11

Description
Adverse effect- Headache
Timepoint
Before starting the study, 5 days after starting treatment, and at the end of treatment
Method of measurement
Ask the patient in person or by phone

12

Description
Adverse effect- Joint pain
Timepoint
Before starting the study, 5 days after starting treatment, and at the end of treatment
Method of measurement
Ask the patient in person or by phone

13

Description
Adverse effect- Asthenia
Timepoint
Before starting the study, 5 days after starting treatment, and at the end of treatment
Method of measurement
Ask the patient in person or by phone

14

Description
Stop treatment
Timepoint
At the end of treatment
Method of measurement
Ask the patient in person or by phone

15

Description
Drug compliance
Timepoint
At the end of treatment
Method of measurement
Good drug compliance: more than 80% intake- Poor

compliance: less than 80% intake. Ask the patient in person or by phone

Intervention groups

1

Description
Intervention group: 5-day treatment group regimen: Amoxicillin: 1000 mg twice daily, Levofloxacin 500 mg once daily (Tavanex®, abidi pharma), Pantoprazole 40 mg twice daily (abidi Pharma) for 5 days
Category
Treatment - Drugs

2

Description
Control group: 10-day treatment group regimen: Amoxicillin: 1000 mg twice daily, Levofloxacin 500 mg once daily (Tavanex®, Abidi pharma), Pantoprazole 40 mg twice daily (Abidi pharma) for 10 days
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ayatollah Rohani hospital
Full name of responsible person
Amin Vahedi
Street address
Ayatollah Rohani hospital, Ganj Afrooz ave.
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Babol
Province
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Postal code
4717641367
Phone
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Email
Dr.aminvahedi@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Mehdi Rajabnia
Street address
Endoscopy ward, Ayatollah Rohani hospital, Ganj Afrooz ave.
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Dr.aminvahedi@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Babol 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
Babol University of Medical Sciences
Full name of responsible person
Amin Vahedi
Position
Researcher
Latest degree
Medical doctor
Other areas of specialty/work
General Practitioner
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Position
Researcher
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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
No further information available.
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be 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