Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of the effectiveness of triple and quadruple therapy regimens for Helicobacter pylori eradication in patients with positive stool exam: A randomized, single-blind clinical trial study

Protocol summary

Study aim

Determining and comparing the effectiveness of two triple and quadruple treatment regimens for Helicobacter pylori eradication in patients referred to Imam Ali Clinic, Shahrekord

Design

A phase 3, single-blind, randomized, controlled clinical trial on 126 patients with Helicobacter pylori who were randomly assigned to two groups A and B. 126 cards, 63 of which had the letter A written on them and the other 63 had the letter B written on them, were placed in an envelope in a jumbled manner, and one card was randomly drawn for each patient. The letter appearing on the card indicated the patient's treatment group.

Settings and conduct

This clinical trial study will be conducted on 126 patients with Helicobacter pylori in Imam Ali clinic of Shahrekord. Patients will be randomly assigned to two groups A and B and will undergo 14-day treatment with eradication regimens. primary outcome: the eradication rate of Helicobacter pylori as defined by a negative stool antigen test. Secondary outcomes: adherence to treatment, clinical symptoms of patients, the rate of side effects during treatment. This study is single-blinded, meaning that the intervention is performed by another person and the researcher is unaware of the type of grouping.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Helicobacter pylori positive First attempt to eradicate Helicobacter pylori Age over 18 years No previous Helicobacter treatment Exclusion criteria: Pregnancy Antibiotic consumption

Intervention groups

Group A: For 14 days: PPI: Esomeprazole 40 mg BID Amoxicillin 1000 mg TDS Bismuth subcitrate 120 mg BD Group B: Bismuth quadruple therapy for 14 days: PPI: Esomeprazole 40 mg BID Tetracycline 500 mg QID Metronidazole 500 mg TDS Bismuth subcitrate 120 mg QID

Main outcome variables

Negative stool antigen test 4 weeks after the end of treatment Side effect Symptoms of the disease

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250227064868N1**
Registration date: **2025-05-02, 1404/02/12**
Registration timing: **registered_while_recruiting**

Last update: **2025-05-02, 1404/02/12**
Update count: **0**

Registration date

2025-05-02, 1404/02/12

Registrant information

Name
Ali Sanei Dehkordi
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 38 3222 8693
Email address
sanei@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-04-05, 1404/01/16

Expected recruitment end date

2025-06-06, 1404/03/16

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effectiveness of triple and quadruple therapy regimens for Helicobacter pylori eradication in patients with positive stool exam: A randomized, single-blind clinical trial study

Public title
Comparison of the effectiveness of triple and quadruple therapy regimens for Helicobacter pylori eradication in patients with positive stool antigen test
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Helicobacter pylori positive Patients with first attempt at Helicobacter pylori eradication Age over 18 years
Exclusion criteria:
previous treatment for Helicobacter pylori eradication pregnancy or breastfeeding previous treatment for eradication of Helicobacter pylori malignant neoplasms history of gastrectomy history of allergy or adverse reactions to the study drugs history of use of PPIs and Potassium-Competitive Acid Blockers in the 2 weeks prior to randomization hematological disease, central nervous system infection, infectious mononucleosis, glucose-galactose malabsorption, lactase deficiency, galactose intolerance, or torsades de pointes Concomitant use of drugs that may interact with the drugs in the present study Withdrawal of consent or failure to complete the final test follow-up Development of drug hypersensitivity or intolerable adverse effects
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **126**
Randomization (investigator's opinion)
Randomized
Randomization description
In this way, 126 cards, 63 of which have the letter A written on them and the other 63 have the letter B written on them, are placed in a jumbled envelope, and one card is drawn at random for each patient. The letter that appears on the card indicates the patient's treatment group.
Blinding (investigator's opinion)
Single blinded
Blinding description
In this study, due to the impossibility of drug matching, blinding is not performed for participants. However, blinding is performed for healthcare personnel (physicians), data collectors, and outcome assessors, and to a lesser extent, the Data Safety and Monitoring Board and those preparing the manuscript.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahrekord Univercity of Medical Sciences
Street address
Kashani Blvd
City
Sharekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8815713471
Approval date
2024-07-31, 1403/05/10
Ethics committee reference number
IR.SKUMS.MED.REC.1403.056

Health conditions studied

1

Description of health condition studied
H.pilory 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
The eradication rate of Helicobacter pylori, which is defined as a negative stool antigen test.
Timepoint
The stool antigen test is performed at the beginning of the study (before the intervention as an inclusion

criterion) and four weeks after the completion of treatment.

Method of measurement
Stool Antigen Test

Secondary outcomes

1

Description
Adherence to treatment

Timepoint
Four weeks after the completion of treatment

Method of measurement
Direct questioning of the patient and writing on the checklist

2

Description
The clinical symptoms of patients (pain, bloating, appetite, heartburn) and the incidence of side effects during treatment as reported by the patients.

Timepoint
After the completion of treatment

Method of measurement
Direct questioning of the patient and writing on the checklist

Intervention groups

1

Description
Intervention group: Treatment regimen A for 14 days containing PPI: Esomeprazole 40 mg BID (Abidi Pharmaceutical Company) - Amoxicillin: 1000 mg TDS (Subhan Pharmaceutical Company) - Bismuth Subcitrate: 120 mg BD (Subhan Pharmaceutical Company)

Category
Treatment - Drugs

2

Description
Intervention group: Treatment regimen B (Bismuth quadruple therapy (BQT) for 14 days) containing PPI: Esomeprazole 40 mg BID (Abidi Pharmaceutical Company) - Tetracycline: 500 mg QID (Subhan Pharmaceutical Company) - Metronidazole: 500 mg TDS (Subhan Pharmaceutical Company) - Bismuth Subcitrate: 120 mg QID (Subhan Pharmaceutical Company)

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Ali Clinic, Shahrekord University of Medical Sciences

Full name of responsible person
Abbas Azari

Street address
Shariati Boulevard, Imam Ali Clinic

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Shahr-e Kord

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahre-kord University of Medical Sciences

Full name of responsible person
Seyed-Mohammad Omrani

Street address
Kashani street

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Web page address
https://en.skums.ac.ir/

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Shahre-kord 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

Shahre-kord University of Medical Sciences

Full name of responsible person
Ali Sanei Dehkordi

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Internal Medicine

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No 3,Faraz Apartment, third Ave, 106 Alley, Kashani Street

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Person responsible for scientific inquiries

Contact

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Position
Resident

Latest degree
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Other areas of specialty/work
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Person responsible for updating data

Contact

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Position
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this 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