

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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)

Phone

+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 University of Medical Sciences

Street address

Kashani Blvd

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Shahrekord

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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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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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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Position

Resident

Latest degree

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Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

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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