Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Efficacy of standard Sequential therapy with Bismuth in Helicobacter pylori Eradication

Protocol summary

Study aim
The effect of bismuth supplementation on the eradication of Helicobacter pylori in sequential therapy

Design
A controlled, parallel-group, double-blind, randomized, phase 3 clinical trial on 124 patients. The website www.sealedenvelope.com/simple-randomiser/v1/lists was used for randomization.

Settings and conduct
In this study, patients referred to the gastroenterology clinic of Shahid Beheshti Hospital, Kashan with symptoms of dyspepsia and a definitive diagnosis of Helicobacter pylori infection were examined. Then, they were randomly assigned to two control groups (standard treatment) and intervention (standard treatment + bismuth) and after the treatment period, stool antigen testing was performed to confirm the eradication of H. pylori infection.

Participants/Inclusion and exclusion criteria
Inclusion criteria: - Patients with functional dyspepsia or gastroduodenal ulcer with indication for eradication of Helicobacter pylori infection - Confirmation of Helicobacter pylori infection by endoscopy pathology result or positive result of Helicobacter pylori stool antigen - Age at least 18 years Non-Inclusion criteria: - Previous eradication of Helicobacter pylori - Use of antibiotics, PPIs or chemotherapy drugs within 4 weeks prior to the study - History of gastrectomy or complicated peptic ulcer - Pregnant and lactating women - Patients with uncompensated renal and heart failure

Intervention groups
Control group: Standard treatment including omeprazole (20 mg every 12 hours) + amoxicillin 500 mg (1000 mg every 12 hours) in the first half of the treatment and omeprazole (20 mg every 12 hours) along with clarithromycin (500 mg every 12 hours) and tinidazole (500 mg twice a day) for two weeks. Intervention group: Standard treatment + bismuth subcitrate 120 mg every 12 hours, 2 tablets for 14 days.

Main outcome variables
Eradication of Helicobacter pylori

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20250529065965N1**
Registration date: **2025-08-10, 1404/05/19**
Registration timing: **retrospective**

Last update: **2025-08-10, 1404/05/19**
Update count: **0**

Registration date
2025-08-10, 1404/05/19

Registrant information
Name
Fatemeh Sadeghi
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 31 5510 9999
Email address
sadeghi.98.1f@gmail.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2024-04-08, 1403/01/20
Expected recruitment end date
2024-10-22, 1403/08/01
Actual recruitment start date
2024-04-08, 1403/01/20
Actual recruitment end date
2024-07-22, 1403/05/01

Trial completion date
2024-10-22, 1403/08/01

Scientific title
The Efficacy of standard Sequential therapy with Bismuth in Helicobacter pylori Eradication

Public title
The Efficacy of Bismuth in Helicobacter pylori Eradication

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with functional dyspepsia or gastroduodenal ulcer who have an indication for eradicating Helicobacter pylori infection Confirmation of Helicobacter pylori infection through pathology results obtained from endoscopy or positive stool antigen test for Helicobacter pylori Minimum age 18 years

Exclusion criteria:
Previous eradication of Helicobacter pylori Use of antibiotics, PPIs, or chemotherapeutic agents within the 4 weeks prior to the study Patients with a history of gastrectomy or complicated peptic ulcer Pregnant and nursing women established.Patients with recompensated kidney and heart failure

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **124**
Actual sample size reached: **120**

Randomization (investigator's opinion)
Randomized

Randomization description
First, the intervention group was coded with the letter A and the control group with the letter B, and then using the website www. sealedenvelope.com/simple-randomiser/v1/lists randomization list was prepared by selecting a sample size of 124 (two groups of 62) and permuted block randomization method (block size=4). Then, through the obtained randomization list, the subjects included in the study will be assigned to one of the two groups A or B. For example, suppose that in the first four blocks, the permutation method is ABBA, so the first and fourth samples will be assigned to group A and the second and third samples to group B and the same will continue until the last sample (124th person).

Blinding (investigator's opinion)
Single blinded

Blinding description
The laboratory (Infection Eradication Evaluator) will be blinded to the study group.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Working Group/Committee, Faculty of Medicine and Dentistry, Kashan University of Med

Street address
Ethics Committee, Vice-Chancellor for Research and Technology, Kashan University of Medical Sciences, Qotb-e Ravandi Boulevard, Kashan, Isfahan Province, Iran

City
Kashan

Province
Isfehan

Postal code
8715973474

Approval date
2023-10-01, 1402/07/09

Ethics committee reference number
IR.KAUMS.MEDNT.REC.1402.154

Health conditions studied

1

Description of health condition studied
Helicobacter pylori

ICD-10 code
B98.0

ICD-10 code description
Helicobacter pylori [H.pylori]

Primary outcomes

1

Description
Eradication of Helicobacter pylori infection

Timepoint
After the end of the antibiotic treatment period, omeprazole treatment was continued for 4 weeks, and eradication of the infection was measured two weeks after omeprazole was discontinued.

Method of measurement
Fecal antigen test

Secondary outcomes

1

Description

Side effects of treatment (bitter taste in the mouth, black stool, diarrhea, nausea, vomiting)

Timepoint

After the treatment period

Method of measurement

Patient self-expression

Intervention groups

1

Description

Intervention group: Standard treatment (omeprazole capsules produced by Iran Darou Company (20 mg every 12 hours), amoxicillin capsules 500 ml produced by Al-Hawi Pharmaceutical Company (1000 mg every 12 hours) in the first half of the treatment and omeprazole capsules produced by Iran Darou Company (20 mg every 12 hours) along with clarithromycin tablets produced by Tehran Shimi Company (500 mg every 12 hours) and tinidazole produced by Pars Darou Company (500 mg twice a day) for two weeks) + bismuth subcitrate 120 mg produced by Iran Darou Company, which is given to patients 2 tablets every 12 hours for 14 days

Category

Treatment - Drugs

2

Description

Control group: Standard treatment includes omeprazole capsules produced by Iran Darou Company (20 mg every 12 hours), amoxicillin capsules 500 ml produced by Al-Hawi Pharmaceutical Company (1000 mg every 12 hours) in the first half of the treatment and omeprazole capsules produced by Iran Darou Company (20 mg every 12 hours) along with clarithromycin tablets produced by Tehran Shimi Company (500 mg every 12 hours) and tinidazole produced by Pars Darou Company (500 mg twice a day) for two weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital of Kashan

Full name of responsible person

Mohammad Reza Sharif

Street address

Shahid Beheshti Hospital, Qotb-e Ravandi Boulevard, Kashan, Isfahan Province, Iran

City

Kashan

Province

Isfehan

Postal code

8715973447

Phone

+98 31 5500 9999

Email

beheshtihospital@kaums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Gholamali Hamidi

Street address

Vice-Chancellor for Research and Technology, Kashan University of Medical Sciences, Qotb-e Ravandi Boulevard, Kashan, Isfahan Province, Iran

City

Kashan

Province

Isfehan

Postal code

8715988141

Phone

+98 31 5558 9399

Email

research@kaums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kashan 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

Kashan University of Medical Sciences

Full name of responsible person

Fatemeh Sadeghi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

Street address

Internal Medicine Department, Shahid Beheshti Hospital, Qotb-e Ravandi Boulevard, Kashan, Isfahan

Province, Iran

City
Kashan

Province
Isfehan

Postal code
8715973447

Phone
+98 31 5500 9999

Email
Sadeghi.98.1f@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Kashan University of Medical Sciences

Full name of responsible person
Abbas Arj

Position
Associate professor

Latest degree
Subspecialist

Other areas of specialty/work
Internal Medicine

Street address
Internal Medicine Department, Shahid Beheshti Hospital, Qotb-e Ravandi Boulevard, Kashan, Isfahan Province, Iran

City
Kashan

Province
Isfehan

Postal code
8715973447

Phone
+98 31 5500 9999

Email
dr_arj@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Kashan University of Medical Sciences

Full name of responsible person
Fatemeh Sadeghi

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Internal Medicine

Street address
Internal Medicine Department, Shahid Beheshti Hospital, Qotb-e Ravandi Boulevard, Kashan, Isfahan Province, Iran

City
Kashan

Province
Isfehan

Postal code
8715973447

Phone
+98 31 5500 9999

Email
Sadeghi.98.1f@gmail.com

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