Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Evaluating the Impact of Rosuvastatin as an Adjuvant to Helicobacter pylori Eradication Regimen on Eradication Rates in Patients with Positive Helicobacter Pylori

Protocol summary

Study aim

To determine the effect of adding rosuvastatin to the standard Helicobacter pylori eradication regimen on the eradication rate.

Design

A phase 3, randomized, double blind, placebo controlled, parallel clinical trial will be conducted in 208 patients with one to one allocation. Block randomization with variable block sizes of 4 and 6 will be performed using Random Allocation Software.

Settings and conduct

The study will be conducted at Emam Khomeini Hospital in Ardabil. Rosuvastatin and placebo will be packaged and coded by an independent pharmacist. Participants and treating physicians will be blinded to group allocation, and the data analyst will remain blinded until completion of the final analysis.

Participants/Inclusion and exclusion criteria

Patients aged 18 years or older with upper gastrointestinal symptoms and Helicobacter pylori infection confirmed by stool antigen testing will be included. Major exclusion criteria include previous gastric surgery or eradication therapy, use of antibiotics, proton pump inhibitors, histamine receptor blockers, or nonsteroidal anti inflammatory drugs during the previous month, allergy to study antibiotics, gastrointestinal malignancy or bleeding, pregnancy, and breastfeeding.

Intervention groups

The intervention group will receive levofloxacin 500 milligrams daily, esomeprazole 40 milligrams every 12 hours, amoxicillin 2 grams daily, and rosuvastatin 20 milligrams daily for 14 days. The control group will receive the same standard regimen plus matching rosuvastatin placebo.

Main outcome variables

Helicobacter pylori eradication one month after completion of treatment, assessed by stool antigen testing.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260929071236N1**
Registration date: **2026-10-05, 1405/07/13**
Registration timing: **prospective**

Last update: **2026-10-05, 1405/07/13**
Update count: **0**

Registration date

2026-10-05, 1405/07/13

Registrant information

Name

Mahsa Mahdavirad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 45 3232 2382

Email address

mahsa.mahdavi·٤٥@gamil.com

Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-11-22, 1405/09/01

Expected recruitment end date

2027-08-21, 1406/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluating the Impact of Rosuvastatin as an Adjuvant to Helicobacter pylori Eradication Regimen on Eradication Rates in Patients with Positive Helicobacter Pylori

Public title
Effect of Rosuvastatin on Helicobacter pylori Eradication

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age 18 years or older Presence of upper gastrointestinal symptoms related to Helicobacter pylori infection Confirmed Helicobacter pylori infection based on stool antigen testing Provision of informed consent to participate in the study

Exclusion criteria:
History of gastric surgery History of previous Helicobacter pylori eradication therapy Use of antibiotics, proton pump inhibitors, histamine receptor blockers, or non-steroidal anti-inflammatory drugs during the previous month Known allergy to any of the antibiotics used in the study Presence of gastrointestinal malignancy Presence of gastrointestinal bleeding Pregnancy Breastfeeding

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **208**

Randomization (investigator's opinion)
Randomized

Randomization description
The unit of randomization is the individual participant. Eligible participants will be allocated to the intervention and control groups in a 1:1 ratio. Block randomization with variable block sizes of 4 and 6 will be used. The random allocation sequence will be generated using Random Allocation Software. No stratified randomization will be used. To ensure allocation concealment, rosuvastatin and matching placebo will be packaged and labeled with numerical codes by an independent pharmacist. The allocation codes will be kept by the independent pharmacist, and individuals involved in participant enrollment and clinical care will not have access to the contents of the coded packages. The allocation codes will remain concealed until completion of the final data analysis.

Blinding (investigator's opinion)
Double blinded

Blinding description
Participants, physicians and other clinical care providers, investigators, outcome assessors, and the data analyst will be blinded to participants' allocation to the intervention or control group. Rosuvastatin 20 mg and placebo without active ingredients will be prepared to be indistinguishable in appearance, color, size, and packaging. Preparation, packaging, and coding of the active drug and placebo will be performed by an independent pharmacist who will not be involved in participant enrollment, clinical care, outcome assessment, or data analysis. The medication packages will be identified only by numerical codes, and the information linking the codes to treatment allocation will be retained by the independent pharmacist. Participants, clinical care providers, investigators, and outcome assessors will not have access to the allocation code during the study. Data analysis will also be performed using coded study groups without the data analyst being aware of the assigned intervention. The allocation code will be revealed only after completion of the final data analysis.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committees of Ardabil University of Medical Sciences

Street address
Vice-Chancellery for Research and Technology, Ardabil University of Medical Sciences, North Side of the University Administrative Complex, University Square, University Street

City
Ardabil

Province
Ardabil

Postal code
5618985991

Approval date
2026-08-26, 1405/06/04

Ethics committee reference number
IR.ARUMS.REC.1405.163

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

Percentage of participants with successful eradication of Helicobacter pylori infection

Timepoint

One month after completion of the 14 day treatment course

Method of measurement

Helicobacter pylori stool antigen test

Secondary outcomes

1

Description

Percentage of participants experiencing at least one treatment related adverse event

Timepoint

At the follow up visit one month after completion of the 14 day treatment course

Method of measurement

Face to face interview with the participant using a predefined adverse event checklist including headache, epigastric pain, nausea, diarrhea, and other unwanted symptoms

Intervention groups

1

Description

Intervention group: Participants will receive the standard triple Helicobacter pylori eradication regimen for 14 days, consisting of oral levofloxacin 500 mg once daily, oral esomeprazole 40 mg every 12 hours, and a total of 2 g oral amoxicillin daily. In addition, they will receive oral rosuvastatin 20 mg once daily for 14 days.

Category

Treatment - Drugs

2

Description

Control group: Participants will receive the standard triple Helicobacter pylori eradication regimen for 14 days, consisting of oral levofloxacin 500 mg once daily, oral esomeprazole 40 mg every 12 hours, and a total of 2 g oral amoxicillin daily. In addition, they will receive one rosuvastatin placebo tablet daily for 14 days. The placebo will contain no active ingredient and will be matched to rosuvastatin in appearance, color, size, and packaging.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Khomeini Hospital

Full name of responsible person

Shahriar Movasagh

Street address

Emam Khomeini Hospital, Shahid Noei Aghdam Brothers Street

City

Ardabil

Province

Ardabil

Postal code

5618985991

Phone

+98 45 3325 1401

Email

Emamhe@arums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

Mohsen Arzanlou

Street address

Vice-Chancellery for Research and Technology, Ardabil University of Medical Sciences, North Side of the University Administrative Complex, University Square, University Street

City

Ardabil

Province

Ardabil

Postal code

5618985991

Phone

+98 45 3353 4757

Email

research@arums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ardabil 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

Ardabil University of Medical Sciences

Full name of responsible person

Mahsa Mahdavirad

Position

Internal Medicine Resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

Street address

Emam Khomeini Hospital, Shahid Noei Aghdam Brothers Street

City

Ardabil

Province

Ardabil

Postal code

5618985991

Phone

+98 45 3326 2140

Email

mahsa.mahdavi045@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

Shahryar Movassagh

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

Street address

Emam Khomeini Hospital, Shahid Noei Aghdam Brothers Street

City

Ardabil

Province

Ardabil

Postal code

5618985991

Phone

+98 45 3326 2140

Email

shahryarmovassagh@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

Mahsa Mahdavirad

Position

Internal Medicine Resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

Street address

Emam Khomeini Hospital, Shahid Noei Aghdam Brothers Street

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Province

Ardabil

Postal code

5618985991

Phone

+98 45 3326 2140

Email

mahsa.mahdavi045@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