

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

Determining and comparing the effect of probiotic(Sabular) and Rosuvastatin on the success of four-drug treatment to eradicate Helicobacter pylori in patients referred to the Gastrointestinal Clinic of Al-Zahra Hospital from December 2023 to March 2025

Protocol summary

Study aim

Determining and comparing the effect of adding probiotics (Sabular) or Rosuvastatin on the success of the standard four-drug treatment to eradicate Helicobacter pylori

Design

This single-blind clinical trial has 3 groups including a control group and two groups of cases 1 and 2. The selection of people in each group is based on the table of random numbers, which includes 85 people in each group.

Settings and conduct

The study will be conducted on patients referred to the gastroenterology clinic of Al-Zahra Educational and Remedial Center in Isfahan from the winter of 2024 to the winter of 2025. Patients are divided into 3 groups. All participants will receive a standard four-drug H. pylori regimen. the control group will receive a placebo drug. Group 1 will be given Sabular probiotics and Group 2 will be given Rosuvastatin. All medicines will be taken for 2 weeks.

Participants/Inclusion and exclusion criteria

Inclusion criteria : Age 18-80 years Having a positive stool antigen test for H. pylori Having at least one of the indications for treatment of H. Pylori Non-entry criteria: Pregnancy and breastfeeding at the time of study Immune deficiency Recent history of Macrolide use Allergy to Penicillin not using Statin and Probiotic treatment at the time of study The presence of contraindications to Rosuvastatin use

Intervention groups

Control group: receiving a standard four-drug regimen of h.pylori including omeprazole + clarithromycin + amoxicillin + bismuth Case 1 group, in addition to the above four-drug treatment, a Sabular probiotic (Saccharomyces Boulardii) is given twice a day. Case 2

group, in addition to the treatment of the above four drugs, Rosvastatin 10 mg is given daily. All medicines will be taken for 2 weeks

Main outcome variables

Helicobacter fecal antigen test result, 4 weeks after the treatment of the disease

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230827059280N1**

Registration date: **2023-10-09, 1402/07/17**

Registration timing: **prospective**

Last update: **2023-10-09, 1402/07/17**

Update count: **0**

Registration date

2023-10-09, 1402/07/17

Registrant information

Name

Mohammad Jafari

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-22, 1402/10/01
Expected recruitment end date
2025-03-19, 1403/12/29
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Determining and comparing the effect of probiotic(Sabular) and Rosuvastatin on the success of four-drug treatment to eradicate Helicobacter pylori in patients referred to the Gastrointestinal Clinic of Al-Zahra Hospital from December 2023 to March 2025

Public title
Determining and comparing the effect of probiotic(Sabular) and Rosuvastatin on the success of four-drug treatment to eradicate Helicobacter pylori

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Having a positive stool antigen test for H. pylori Having at least one indication for the treatment of H. Pylori including: 1. Patients with dyspepsia and a positive stool Ag test for H. Pylori, (according to the prevalence >20% of Helicobacter pylori infection in the Iranian population) 2. Patients with resistant dyspepsia and Positive gastric biopsy for Helicobacter in endoscopy 3. Patients with dyspepsia with unknown cause and age less than 60 years who have a positive stool Ag test. 4. Patients with a positive stool Ag test who need long-term treatment with NSAID 5. Patients with early stages of gastric cancer who have undergone resection surgery. 6. Patients with a high risk of gastric cancer (first degree family of a person with gastric cancer, extensive gastritis or severe atrophy of gastric mucosa, history of gastric neoplasm) people treated with gastric acid secretion inhibitors for more than 1 year, the presence of environmental risk factors for stomach cancer or the patient's great fear of stomach cancer)
Exclusion criteria:
Pregnancy and breastfeeding at the time of study
Immune deficiency
Recent history of macrolide use
Allergy to penicillin
Not currently taking statins and probiotics
The presence of contraindications for rosuvastatin use (history of hypersensitivity reaction to rosuvastatin or substances added to the composition of rosuvastatin tablets, increased liver enzymes AST, ALT without a specific cause, acute liver failure, uncompensated liver cirrhosis, pregnancy or breastfeeding)

Age
From **18 years** old to **80 years** old

Gender
Both

Phase
3

Groups that have been masked

• Participant

Sample size
Target sample size: **255**

Randomization (investigator's opinion)
Randomized

Randomization description
Random Allocation version 2 software will be used. Sampling will be done by the method of alternating blocks of 3: 15 blocks of 6 Each block contains 6 letters from letters A, B, and C including ACABCB CCABAB, BBAACC, BABACA, etc. (three groups of 30) Each patient will be given a card randomly. It is in sealed envelopes and the technician takes the envelopes and delivers them to the patients. For people who have card A, standard H.Pylori first-line therapy (Esomeprazole plus Clarithromycin plus Amoxicillin plus Bismuth) are given for two weeks. people who have card B, in addition to the four-drug treatment, Sabular probiotic (SaccharomycesBullardi) twice a day is given. For people with card C, Rosuvastatin 10 mg daily is added to the treatment. A month later after the treatment ends, a specific H. Pylori stool Ag test is performed to prove the eradication of Helicobacter.

Blinding (investigator's opinion)
Single blinded

Blinding description
The method of blinding in this study is the single-blind method. Participants are given drugs with a completely similar appearance. , so they are completely unaware of which study group they are in. Researchers, clinical caregivers, and clinical outcome assessors are fully aware of the classification of patients.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees
1
Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences
Street address
Hezar Jarib St , Isfahan University of Medical Sciences
City
Isfahan
Province
Isfahan
Postal code
81746-73461
Approval date
2023-07-24, 1402/05/02
Ethics committee reference number
IR.MUI.MED.REC.1402.164

Health conditions studied

1

Description of health condition studied

Helicobacter pylori

ICD-10 code

B96.81

ICD-10 code description

Helicobacter pylori [H. pylori] as the cause of diseases classified elsewhere

Primary outcomes

1

Description

Helicobacter pylori stool specific antigen test result

Timepoint

Conducting Helicobacter pylori fecal specific antigen test before the start of the study to determine the criteria for the patient to enter the study and 4 weeks after the completion of the 2-week treatment.

Method of measurement

Helicobacter pylori stool specific antigen test

Secondary outcomes

empty

Intervention groups

1

Description

Control group: This group of patients receives the standard 4-drug regimen for Helicobacter pylori including Esomeprazole plus Clarithromycin plus Amoxicillin plus Bismuth for 2 weeks. In addition to the above drugs, placebos, which are similar in appearance to the drugs of the intervention group, are taken orally daily for 2 weeks.

Category

Placebo

2

Description

Intervention group: In intervention group 1, the patients are given the standard 4-drug regimen for Helicobacter pylori, including Esomeprazole plus Clarithromycin plus Amoxicillin plus Bismuth for 2 weeks. In addition to the above drugs, the probiotic Sabular (Saccharomyces boulardii) is given twice a day for two weeks at the same time. This drug is similar in appearance to the placebo and the drug given to intervention group 2.

Category

Treatment - Drugs

3

Description

Intervention group: In intervention group 1, the patients

are given the standard 4-drug regimen for Helicobacter pylori, including Esomeprazole plus Clarithromycin plus Amoxicillin plus Bismuth for 2 weeks. In addition to the above drugs, Rosuvastatin 10 mg daily for two weeks is given at the same time. This drug is similar in appearance to the placebo and the drug given to intervention group 1.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra hospital

Full name of responsible person

Mohammad Jafari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Esfahan 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**

Esfahan University of Medical Sciences

Full name of responsible person

Mohammad Jafari

PositionAssistant Professor of Gastroenterology and
Hepatology**Latest degree**

Subspecialist

Other areas of specialty/work

Gastroenterology and Hepatology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

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Position

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The participant's data will be fully available after removing personal information, study protocol, statistical analysis plan, informed consent form without personal information, and clinical study report.

When the data will become available and for how long

Since the publication of results in authoritative articles

To whom data/document is available

will be available to the public

Under which criteria data/document could be used

There is no limitation to access information and data

From where data/document is obtainable

Dr. Mohammaad Jafari: m.jafari@mui.ac.ir

What processes are involved for a request to access

data/document

By sending an e-mail, the applicant states the request and the reason for the request, and the documents will

be sent to him within a possible period of one month and after the review of his request

Comments