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)

Phone
+98 31 3822 7000

Email address
m.jafari@med.mui.ac.ir

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

Isfehan

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 Heliobacter 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 Heliobacter 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
Street address
Alzahra Medical & Education Center, Sofe Blvd
City
Isfahan
Province
Isfehan
Postal code
8174675731
Phone
+98 31 3822 0000
Email
m.jafari@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Dr. Gholamreza Asgari
Street address
AlZahra hospital, Sofe st
City
Isfahan
Province
Isfehan
Postal code
7573181746
Phone
+98 31 3822 0000
Email
m.jafari@med.mui.ac.ir
Web page address
https://alzahra.mui.ac.ir/
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
Position
Assistant Professor of Gastroenterology and Hepatology
Latest degree
Subspecialist
Other areas of specialty/work
Gastroenterology and Hepatology
Street address
AlZahra Hospital, Sofe Blvd
City
Isfahan
Province
Isfehan
Postal code
7573181746
Phone
+98 31 3822 0000
Email
m.jafari@med.mui.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Mohammad Jafari
Position
Assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
Internal Medicine
Street address
AlZahra hospital, Sofeh Blvd, Isfahan
City
Isfahan
Province
Isfehan
Postal code
7573181746
Phone
+98 31 3822 7000
Fax
Email
m.jafari@med.mui.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Fatemeh Keshaei Arani
Position
Internal Medicine Resident
Latest degree
Medical doctor
Other areas of specialty/work
Internal Medicine
Street address
AlZahra Hospital, Sofe Blvd
City
Isfahan
Province
Isfehan
Postal code
7573181746
Phone
+98 31 3822 0000
Email
keshaei.f@gmail.com

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