Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 2026

Randomized controlled trial of three Vonoprazan based treatment regimens for eradication of Helicobacter pylori infection: a triple-blind clinical trial study.

Protocol summary

Study aim

Comparison of H. pylori eradication rates among three vonoprazan-based treatment regimens with the shortest treatment duration

Design

The clinical trial will be conducted in a randomized, parallel, triple-blind manner on 330 patients.

Settings and conduct

Patients referred to Motahari Clinic are divided into three groups A, B, and C. Group A patients enter the standard treatment regimen, and group B patients use two mint tablets and green tea in addition to the standard treatment. The secretary randomly gives the patients packets numbered 1 A to A101, 1B to B101, and 1 C to C101, prepared by an independent person. The patients, treating physicians, and the researcher and data analyst are unaware of the type of treatment received. Outcomes are assessed by independent clinical investigators.

Participants/Inclusion and exclusion criteria

Study inclusion criteria: People who have referred to a gastroenterologist and liver specialist with symptoms of indigestion and duodenal ulcer and have a positive pathology test or H. pylori stool antigen. Study exclusion criteria: People who do not have a confirmed H. pylori test or have taken antibiotics for in the past four weeks.

Intervention groups

1. High-dose vonoprazan and high-dose amoxicillin 7 days 2. Vonoprazan-lefloxacin-bismuth and metronidazole 10 days 3. Omeprazole-amoxicillin-metronidazole and bismuth 14 day

Main outcome variables

Percentage of people whose stool antigen test results and clinical symptoms changed after treatment. Stool antigen test measurement and clinical symptoms assessment after treatment.

General information

Reason for update

Acronym

RCTVREHP

IRCT registration information

IRCT registration number: **IRCT20200422047167N2**
Registration date: **2026-07-08, 1405/04/17**
Registration timing: **registered_while_recruiting**

Last update: **2026-07-08, 1405/04/17**
Update count: **0**

Registration date

2026-07-08, 1405/04/17

Registrant information

Name

Seyedeh Azra Shamsdin

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-06-22, 1405/04/01

Expected recruitment end date

2027-02-20, 1405/12/01

Actual recruitment start date

2026-07-06, 1405/04/15

Actual recruitment end date

2027-03-11, 1405/12/20

Trial completion date

2027-03-20, 1405/12/29

Scientific title

Randomized controlled trial of three Vonoprazan based treatment regimens for eradication of Helicobacter pylori infection: a triple-blind clinical trial study.

Public title

Randomized controlled trial of three Vonoprazan based treatment regimens for eradication of Helicobacter pylori infection

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

1- Patients with H. pylori who have a positive written result of urea breath test or stool antigen test or pathological test. 2- Patients who have not received any anti-H. pylori treatment in the past three months. 3- Individuals over 18 years of age.

Exclusion criteria:

1 - Individuals without a confirmed test and a positive written result for H. pylori. 2- Individuals who have been treated for cancer. 3- Patients who have taken antibiotics for any reason in the past four weeks. 4- Patients who have taken immunosuppressive drugs. 5- Individuals with underlying cardiovascular diseases, advanced liver diseases, or renal failure. 6- Pregnant or lactating women.

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **330**

Actual sample size reached: **330**

Randomization (investigator's opinion)

Randomized

Randomization description

lock randomization will be used in a 1:1:1 ratio to randomly and equally allocate participants to three treatment groups. Randomization will be performed by an independent individual from the treatment team to prevent any bias in patient allocation. After applying concealed allocation, patients will be divided into three groups in the following manner: 110 envelopes numbered 1 to 110 A, 110 envelopes numbered 1 to 110 B, and 110 envelopes numbered 1 to 110 C. A trained expert will randomly assign one of the envelopes to the patients, and after obtaining informed consent, they will enter the study.

Blinding (investigator's opinion)

Triple blinded

Blinding description

After applying concealed allocation, the patients were divided into three groups in the following manner: 20 packets numbered 1 to 20 A and 20 packets numbered 1 to 20 B were prepared, and a secretary randomly gave one of the packets to the patients, and the people in group A entered the antibiotic treatment regimen, and the people in group B entered the combination treatment regimen of mint tablets and green tea. After providing the necessary explanations and obtaining informed consent, they entered the study. In this study, people who refer to a specialist at Motahari Clinic in Shiraz with symptoms of heartburn and reflux and have a positive H. pylori sampling or breath test will be included in the study. After obtaining written informed consent from the participants, the randomization process will be performed using a random block method with a ratio of 1:1 so that the participants will be randomly placed in one of the two treatment groups. The first group will receive standard H. pylori treatment including antibiotics and omeprazole for one month. The second group will take two herbal medicines, peppermint (Supermint) and green tea (Camellia sinensis), for one month in addition to the standard treatment. The first group will be given a placebo pill of the same shape and size instead of the herbal medicine. The study is designed as a double-blind study, meaning that neither the patients nor the treating physicians will know which treatment they are receiving. Randomization and coding of the drugs will be performed by an independent person from the treatment team. The drug packages will be provided to the patients in the same way and without a name indicating the type of treatment. The outcome assessment will be performed by an independent team of clinical researchers to avoid any bias. After the treatment period (one month), stool samples will be taken from all patients. Fecal antigens will be measured using a special kit using the ELISA method.

Placebo

Not used

Assignment

Parallel

Other design features

In addition to the primary ITT-based analysis, a secondary Per-Protocol (PP) analysis will be conducted, in which only patients who fully complied with the treatment protocol and completed the study follow-up will be included in the analysis. This analysis is performed to assess the effectiveness of the intervention in the context of full adherence to treatment.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical

Sciences

Street address
Shiraz University of Medical Sciences,Zand Avenue, Shiraz ,Iran

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Shiraz

Province
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7193711351

Approval date
2026-04-27, 1405/02/07

Ethics committee reference number
IR.SUMS.REC.1405.074

Health conditions studied

1

Description of health condition studied
Helicobacter Pylori infection

ICD-10 code
K93

ICD-10 code description
Disorders of other digestive organs in diseases classified elsewhere

Primary outcomes

1

Description
Percentage of people in each of the target groups whose stool antigen test results changed after treatment.

Timepoint
Before starting treatment and after completing the treatment period (6 weeks), stool samples will be taken from all patients to examine Stool Antigen.

Method of measurement
Determination of Helicobacter pylori antigen in feces is measured with a special kit using the ELISA method.

Secondary outcomes

empty

Intervention groups

1

Description
The first Intervention group will receive a drug regimen consisting of 20 mg of vonoprazan four times a day and 1000 mg of amoxicillin four times a day for 7 days. The continuation of this arm will be subject to the results of the interim analysis and subsequent decision-making.

Category
Treatment - Drugs

2

Description
The second Intervention group will receive 20 mg of vonoprazan twice a day and 240 mg of bismuth subcitrate twice a day and 500 mg of amoxicillin four times a day and 500 mg of metronidazole three times a day for 10 days.

Category
Treatment - Drugs

3

Description
The third Intervention group of drug regimens includes omeprazole 20 mg twice a day and bismuth subcitrate 240 mg twice a day and amoxicillin 500 mg four times a day and metronidazole 500 mg three times a day for 14 days.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Motahari Clinic, Shiraz University of Medical Sciences

Full name of responsible person
Seyedeh Azra Shamsdin

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Gastroenterohepatology Research Center,Mohammad Rasoolallah Research Tower,Khalili Street,Shiraz, Iran

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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
Vice President for Research and Technology, Shiraz University of Medical Sciences,Shiraz

Grant code / Reference number
34574

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

Title of funding source
Shiraz 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
Shiraz University of Medical Sciences

Full name of responsible person
Seyedeh Azra Shamsdin

Position
Assistant Professor Immunology

Latest degree
Ph.D.

Other areas of specialty/work
Immunology

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Subspecialist

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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
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Data on the main outcome of participants can be shared after de-identification.
When the data will become available and for how long
Access starts from March 30, 2027
To whom data/document is available
Data will only be available to principal investigators and researchers working in academic and scientific institutions.
Under which criteria data/document could be used
If requested by the supervisor of the project and the reviewers of the article, the authorized data will be provided to the people.
From where data/document is obtainable
Seyedeh Azra Shamsdin
What processes are involved for a request to access data/document
The applicant can request research data by email.
Comments
If the data and their analysis are requested by the supervisor or university referees, they will be provided to them by email.