Clinical Trial Protocol
Iranian Registry of Clinical Trials

23 Jul 2026

Effectiveness of Rosuvastatin -containing quadriple regimen in eradication of Helicobacter pylori infection compared to the standard four-drug regimen in Helicobacter pylori positive patients

Protocol summary

Study aim
Investigating the effectiveness of the quadruple diet along with rosuvastatin in eradicating Helicobacter pylori infection

Design
A clinical trial with a control group with double-blind parallel groups, randomized, phase 3 on 156 patients.

Settings and conduct
Patients referring to Taleghani Hospital will complete a questionnaire that includes demographic information, medical history and medication. H pylori infection will be evaluated by endoscopy or stool antigen. Patients are randomly divided into intervention and control groups. The primary endpoint of the study will be H pylori eradication and the secondary endpoint will be the incidence of treatment-related severe adverse events. Acceptable compliance to diet therapy is defined by taking at least 80% of prescribed drugs. After 4 weeks of treatment, all patients are re-evaluated. The incidence of side effects is determined as an evaluation of the safety of treatment regimens. After the end of the treatment period, the eradication rate of H pylori infection in the two groups and the frequency of side effects in the two groups will be determined and compared.

Participants/Inclusion and exclusion criteria
Inclusion criteria: confirmation of H. pylori infection in patients by standard diagnostic methods, age over 18 years. Exclusion criteria: history of gastric surgery, history of taking statins and antibiotics and non-steroidal and anti-inflammatory drugs, history of active gastrointestinal bleeding

Intervention groups
Intervention group: Patients in this group received rosuvastatin tablets (20 mg) once a day in addition to quadruple therapy (amoxicillin (1 g), clarithromycin (500 mg), metronidazole (500 mg) and omeprazole as a proton pump (40 mg). grams)) will receive for 1 month.
Control group: Patients in this group will consume the quadruple diet twice a day for 14 days.

Main outcome variables
H.pylori eradication

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230314057717N2**
Registration date: **2023-06-21, 1402/03/31**
Registration timing: **prospective**

Last update: **2023-06-21, 1402/03/31**
Update count: **0**

Registration date
2023-06-21, 1402/03/31

Registrant information

Name
Amir Sadeghi

Name of organization / entity

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Iran (Islamic Republic of)

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+98 21 2243 2540

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amirsadaghi@sbmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-07-06, 1402/04/15

Expected recruitment end date
2023-11-22, 1402/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of Rosuvastatin -containing quadriple regimen in eradication of Helicobacter pylori infection compared to the standard four-drug regimen in Helicobacter pylori positive patients

Public title

The effect of the quadruple regimen containing rosuvastatin on the improvement of stomach infection

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Confirmation of H. pylori infection in patients by standard diagnostic methods Age above 18 years Willingness to participate in the study

Exclusion criteria:

Patients are currently being treated with a four-drug regimen

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **156**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are assigned to two groups using the random block method. The number of blocks will be 22 and in each block, two, four or six patients will be included in the study order. Random allocation of blocks of patients to intervention and control treatment groups will be done through Sealed Envelope online software. The randomized list of blocks will be placed in sealed envelopes and will be provided to the gastroenterologist on a daily basis.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study will be blinded for patients, evaluator of drug outcomes and analysis. In this way, patients do not know in which group they are receiving medicine. Also, the evaluator does not know which patient has received which drug regimen during the examination of drug side effects and the rate of recovery of patients. Finally, the data is provided to the analyst in a coded form, and he does not know which data is related to which patient.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address

Arabi street, Velenjak

City

Tehran

Province

Tehran

Postal code

4739-19395

Approval date

2023-05-30, 1402/03/09

Ethics committee reference number

IR.SBMU.MSP.REC.1402.091

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 eradication

Timepoint

Before the intervention and 14 days after the intervention

Method of measurement

Endoscopy or fecal antigen test

Secondary outcomes

1

Description

Occurrence of drug side effects

Timepoint

14 days after the start of the intervention

Method of measurement

Physical examination

Intervention groups

1

Description

Intervention group: Patients in this group received rosuvastatin tablets (20 mg) once a day in addition to quadruple therapy (amoxicillin (1 g), clarithromycin (500 mg), metronidazole (500 mg) and omeprazole as a proton pump (40 mg)). will receive for 1 month. The drug regimen will be provided to the patient in the form of a drug package.

Category

Treatment - Drugs

2

Description

Control group: Patients in this group will take a quadruple regimen including amoxicillin (1 g), clarithromycin (500 mg), metronidazole (500 mg) and omeprazole as a proton pump (40 mg) twice a day for 14 days. The drug regimen will be provided to the patient in the form of a drug package for a period of 14 days.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Gastroenterology and Liver Clinic, Taleghani Hospital

Full name of responsible person

Mohammad Javad Ehsani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

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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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Shahrzad Salimi

Position

Rezident

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Position
Associate professor

Latest degree
Subspecialist

Other areas of specialty/work
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Person responsible for updating data

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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
Yes - There is 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
Regarding the release of data, only data related to the consequences of taking drugs can be released. Other patient information will not be reported

When the data will become available and for how long
After the publication of the article

To whom data/document is available
Researchers, students and professors

Under which criteria data/document could be used
The data can be used if information is provided regarding the method of analysis, if the principle of referencing is observed

From where data/document is obtainable
Send an email to the corresponding author Dr. Amir Sadeghi Amirsadeghimd@yahoo.com

What processes are involved for a request to access data/document
Send the request to the responsible author via email and explain the details of the required data and mention the reason and how to use it

Comments