Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jul 2026

Evaluation of the effect of adding Atorvastatin to standard treatment in Helicobacter pylori eradication

Protocol summary

Study aim
Considering the role of Helicobacter and the importance of eradication of this bacterium, we are finding a way to increase the success rate of Helicobacter pylori eradication compared to the existing standard treatment to reduce the complications of infection of this bacterium.

Design
A single-blind randomized clinical trial study The 120 patients will be divided into two groups of 60 in the control group (receiving standard treatment) and the intervention group (receiving Atorvastatin in addition to standard treatment) based on a random number table.

Settings and conduct
Outpatient Clinic of Imam Khomeini Hospital Patients are unaware of each other's treatment The control group receiving standard treatment, the other group added Atorvastatin to standard treatment, and after 4 weeks of treatment, all patients would undergo assess fecal Helicobacter pylori antigens

Participants/Inclusion and exclusion criteria
Age >= 18 years Absence of concurrent liver disease Absence of concurrent diabetes Not using statin in the past 6 months No history of gastric surgery No history of receiving H.pylori eradication therapy No antibiotics, PPI, H2 blockers, anti-inflammatory drugs and NSAIDs, bismuth salts in the past month No allergy to any of the antibiotics used in the study Absence of gastrointestinal malignancy No active gastrointestinal bleeding Non-pregnant and non-lactating No history of radiation therapy

Intervention groups
Standard treatment (a Bismuth Subcitrate 240 mg tablet, a Pantoprazole 40 mg tablet, a metronidazole 500mg tablet, and 2 amoxicillin 500mg capsules, all every 12 hours for 14 days) is prescribed for all patients and patients in the intervention group in addition to standard treatment with Atorvastatin 40mg daily for 14 days

Main outcome variables
Eradication of Helicobacter pylori

General information

Reason for update

Acronym
AHBPE

IRCT registration information
IRCT registration number: **IRCT20190823044589N1**
Registration date: **2019-12-28, 1398/10/07**
Registration timing: **retrospective**

Last update: **2019-12-28, 1398/10/07**
Update count: **0**

Registration date
2019-12-28, 1398/10/07

Registrant information

Name
Parham Porteghali

Name of organization / entity

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Iran (Islamic Republic of)

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+98 44 3198 8002

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-04-21, 1398/02/01

Expected recruitment end date
2019-12-21, 1398/09/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effect of adding Atorvastatin to standard treatment in Helicobacter pylori eradication

Public title
Effect of Atorvastatin in Helicobacter pylori eradication

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
18 years or older Indication for Helicobacter pylori eradication

Exclusion criteria:
liver disease at the same time Diabetes at the same time Statin use in 6 months History of gastric surgery History of treatment for eradication of H. pylori Antibiotics, PPIs, histamine receptor blockers, anti-inflammatory and non-steroidal drugs, bismuth salts in the past month Allergy to any of the antibiotics used in the study Gastrointestinal malignancy Active gastrointestinal bleeding Pregnant and lactating History of radiation therapy

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomly based on random number table

Blinding (investigator's opinion)
Single blinded

Blinding description
Patients don't know medications other patients receive for treatment

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Urmia University of Medical Sciences

Street address
West Azarbaijan University of Medical Sciences and Health services, next to emergency department, Jahad St., Resalat Boulevard

City
Urmia

Province
West Azarbaijan

Postal code
5714783734

Approval date
2019-07-31, 1398/05/09

Ethics committee reference number
IR.UMSU.REC.1398186

Health conditions studied

1

Description of health condition studied
Helicobacter pylori infection

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Helicobacter pylori eradication

Timepoint
After 4 weeks of completion of treatment

Method of measurement
38/5000Evaluation of Helicobacter pylori fecal antigen

Secondary outcomes

1

Description
Drug Side effects

Timepoint
During and after the course of treatment

Method of measurement
Ask the patient

Intervention groups

1

Description
Intervention group: Atrostatin 40 mg at night for 14 days with standard treatment (including a Bismuth Subcitrate 240 mg tablet, a Pantoprazole 40 mg tablet, a metronidazole 500 mg tablet, and 2 x amoxicillin 500 mg capsules, all every 12 hours for 14 days)

Category
Treatment - Drugs

2

Description
Control group: Standard treatment for 14 days (including a Bismuth Subcitrate 240 mg tablet, a Pantoprazole 40 mg tablet, a metronidazole 500 mg tablet, and 2 x amoxicillin 500 mg capsules, all every 12 hours for 14 days)
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Oroumia 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
Oroumia University of Medical Sciences
Full name of responsible person
Mohammad Reza Mohammad Hosseini Azar
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
All underlying information, grouping and the result of treatment of patients without mentioning the name of the patient in Excel and SPSS files are recorded and presented.
When the data will become available and for how long
6 months after the article to be published
To whom data/document is available
All academic and non-academic person
Under which criteria data/document could be used
In order to request the results and outputs of data analysis in the SPSS software, after submitting the application and approval of Urmia University of Medical Sciences, statistical outputs will be provided.
From where data/document is obtainable
Vice chancellor for research and technology of Urmia University of Medical Sciences
What processes are involved for a request to access data/document
After submitting the application and approval of the Deputy of research and Technology of Urmia University of Medical Sciences, the results will be sent during the maximum one month period by researcher.
Comments