Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of three-drug and consecutive treatment regimens in the eradication of Helicobacter pylori in patients referred to the gastrointestinal clinic of Imam Khomeini Hospital in Urmia

Protocol summary

Study aim
Comparison of three-drug and consecutive treatment regimens in the eradication of Helicobacter pylori in patients referred to the gastrointestinal clinic of Imam Khomeini Hospital in Urmia

Design
On 270 patients (in groups of 90 people)

Settings and conduct
Gastroenterology Clinic of Imam Khomeini Hospital in Urmia

Participants/Inclusion and exclusion criteria
Inclusion criteria 1- Endoscopically confirmed primary Helicobacter pylori infection 2- Having dyspepsia for at least 6 months or more 3- No history of taking any antibiotics during the last month and no history of taking proton pump inhibitors And antacids in a recent month and exclusion criteria: 1- Upper gastrointestinal surgery, gastric cancer, kidney and liver failure 2- Pregnancy and lactation 3- Age under 18 4- Allergy to the studied drugs 5- Alcohol consumption in patients 6- Patients receiving antiarrhythmic drugs

Intervention groups
Group 1: omeprazole 20mg twice daily + amoxicillin 1 g twice daily + clarithromycin 500mg twice daily for 10 days Group 2: omeprazole 20mg twice daily + amoxicillin 1 g daily for 2 weeks + levofloxacin 500mg twice daily in the first week of the diet Group 3: omeprazole 20mg twice daily + amoxicillin one gram twice daily for 5 days + metronidazole 500mg twice daily for the second 5 days + clarithromycin 500mg twice daily for the second 5 days that (these drugs are routine drugs It was used to treat patients. Then, after the end of treatment, patients were evaluated for side effects of drugs. Patients went to the clinic 2 weeks, 6 weeks and 10 weeks after starting treatment.

Main outcome variables
Reduce complications and improve the condition of the disease

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200907048643N1**
Registration date: **2020-09-14, 1399/06/24**
Registration timing: **retrospective**

Last update: **2020-09-14, 1399/06/24**
Update count: **0**

Registration date
2020-09-14, 1399/06/24

Registrant information

Name
Omid garkaz

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 23 3232 5054

Email address
omid.garkaz23@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-03-21, 1397/01/01

Expected recruitment end date
2019-03-20, 1397/12/29

Actual recruitment start date
2019-03-20, 1397/12/29

Actual recruitment end date
2019-03-20, 1397/12/29

Trial completion date
2019-03-20, 1397/12/29

Scientific title
Comparison of three-drug and consecutive treatment regimens in the eradication of Helicobacter pylori in patients referred to the gastrointestinal clinic of Imam Khomeini Hospital in Urmia

Public title
Comparison of three-drug and consecutive treatment regimens in the eradication of Helicobacter pylori in patients referred to the gastrointestinal clinic of Imam Khomeini Hospital in Urmia
Purpose
Diagnostic
Inclusion/Exclusion criteria
Inclusion criteria:
1- Endoscopic primary infection of Helicobacter pylori 2- Have symptoms of dyspepsia for at least 6 months or more 3- No history of taking any antibiotics during the last month and no history of taking proton and antacid pump inhibitors in the last month
Exclusion criteria:
1- Endoscopic primary infection of Helicobacter pylori 2- Have symptoms of dyspepsia for at least 6 months or more 3- No history of taking any antibiotics during the last month and no history of taking proton and antacid pump inhibitors in the last month
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **270**
Actual sample size reached: **270**
Randomization (investigator's opinion)
Randomized
Randomization description
Gastrointestinal patients were selected after entering the gastrointestinal clinic and were randomly divided into three groups. A total of 270 patients were selected in groups of 90 with three, The groups were divided into each of which was randomly given one of the drug groups.The tool for making random blocks was https://www.sealedenvelope.com.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Urmia University of Medical Sciences
Street address
Resalat Street, next to the provincial emergency room
City
Urima
Province
West Azarbaijan
Postal code
5714783734
Approval date
2018-10-03, 1397/07/11
Ethics committee reference number
IR.UMSU.REC.1397.239

Health conditions studied

1

Description of health condition studied
Comparison of three-drug and consecutive treatment regimens in eradication of Helicobacter pylori in patients referred to the gastrointestinal clinic of Imam Khomeini Hospital in Urmia
ICD-10 code
K20
ICD-10 code description
Oesophagitis

Primary outcomes

1

Description
Helicobacter pylori treatment
Timepoint
Patients were referred to the clinic 2 weeks, 6 weeks and 10 weeks after starting treatment. Patients were examined for Helicobacter pylori by Stool Ag test. Individuals who were registered for successful negative test treatment for H. pylori eradication. In the second week visit, all side effects including (bad taste, dry mouth, diarrhea, confusion, tongue burn, nausea and vomiting, abdominal pain, constipation and headache) and patient compliance were recorded based on the number of pills remaining and then four weeks PPI only It was taken and then they did not take any PPI and antibiotics for 4 weeks and then it was proved by Stool Ag eradication of Helicobacter pylori infection in each group.
Method of measurement
Blood and stool tests

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: First group: omeprazole 20mg twice daily + amoxicillin one gram twice daily + clarithromycin 500mg twice daily for 10 days Second group: omeprazole 20mg twice daily + amoxicillin one gram daily for 2 weeks + levofloxacin 500mg Twice a day in the first week of the diet and the third group: omeprazole 20mg twice daily + amoxicillin one gram twice daily for 5 days + metronidazole 500mg twice daily for the second 5 days + clarithromycin 500mg twice daily for 5 second day

Category
Treatment - Drugs

2

Description
Intervention group: Group 2: omeprazole 20mg twice daily + amoxicillin 1 g daily for 2 weeks + levofloxacin 500mg twice daily in the first week of the diet

Category
Treatment - Drugs

3

Description
Intervention group: Group 3: omeprazole 20mg twice daily + amoxicillin one gram twice daily for 5 days + metronidazole 500mg twice daily for the second 5 days + clarithromycin 500mg twice daily for the second 5 days

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Gastroenterology Clinic of Imam Khomeini Hospital, Urmia, with indication for eradication of Helicob

Full name of responsible person
Hamid Reza Mehryar

Street address
Resalat Steret

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5714783734

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omid.garkaz23@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Oroumia University of Medical Sciences

Full name of responsible person
Dr. Iraj Mohebbi

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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
1

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
Hamid Reza Mehryar

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Emergency Medicine

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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
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
It is about the best treatment.
When the data will become available and for how long
Always
To whom data/document is available
Researcher
Under which criteria data/document could be used
Always
From where data/document is obtainable
Patients referred to the gastrointestinal clinic
What processes are involved for a request to access data/document
It does not have a specific process
Comments