

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 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

Urmia

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

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Phone

+98 44 3223 4897

Email

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

Street address

Streat Resalt

City

Urima

Province

West Azarbaijan

Postal code

5714783734

Phone

+98 44 3223 4897

Email

omid.garkaz23@gmail.com

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

Street address

Streat Resalt

City

Urima

Province

West Azarbaijan

Postal code
5714783734
Phone
+98 44 3223 4897
Email
omid.garkaz23@gmail.com

Person responsible for scientific 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
Street address
Resalt Street
City
Urima
Province
West Azarbaijan
Postal code
5714783734
Phone
+98 44 3223 4897
Email
Hamidrezamehryar2010@gmail.com

Person responsible for updating data

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
Street address
Resalat Street
City
Urima
Province
West Azarbaijan
Postal code
5714783734
Phone
+98 44 3223 4897
Email
Hamidrezamehryar2010@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

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