Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

A comparison between triple and quadruple therapy efficacy in eradication of Helicobacter pylori in patients with dyspepsia referred to gastrointestinal clinic of Shohada-Ashayer and Shahid Rahimi hospitals of Khorramabad in 2015

Protocol summary

Summary
The aim of this study is to compare the effectiveness of triple (classic) therapy with quadruple therapy in the eradication of Helicobacter pylori in patients with dyspepsia patients admitted to the gastrointestinal clinics of Shohada and Rahimi hospitals of Khorramabad. The inclusion criteria consist of being diagnosed with Helicobacter pylori, being indicated for the eradication of Helicobacter pylori, being older than 18, not having allergy to any of the medications used in the study, and not having a history of H. pylori eradication. In addition, a recent history (last month) of antibiotic therapy in each patient and pregnancy are considered as the exclusion criteria.The sample size in each group is 107.This study is designed as medicinal interventionand nutritional control. The intended duration is 6 weeks. The primary consequence of the study is the eradication of Helicobacter pylori.

General information

Acronym
IRCT registration information
IRCT registration number: **IRCT2016012623736N2**
Registration date: **2016-02-25, 1394/12/06**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**
Registration date
2016-02-25, 1394/12/06

Registrant information
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Recruitment status
Recruitment complete
Funding source
Lorestan University of Medical Sciences

Expected recruitment start date
2016-02-20, 1394/12/01
Expected recruitment end date
2017-02-19, 1395/12/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
A comparison between triple and quadruple therapy efficacy in eradication of Helicobacter pylori in patients with dyspepsia referred to gastrointestinal clinic of Shohada-Ashayer and Shahid Rahimi hospitals of Khorramabad in 2015

Public title
A comparison between triple and quadruple therapy efficacy in eradication of Helicobacter pylori in patients with dyspepsia
Purpose
Treatment
Inclusion/Exclusion criteria

Inclusion criteria: The age of greater than 40 years; A positive family history of gastric cancer or patients who have signs and symptom sof gastric cancer; Also patients among whom, the symptoms have not ameliorated; despite a 6-week PPI therapy; and who have a positive biopsy. Exclusion criteria: Age less than 18 years; A positive history of allergic reaction to each of the medications used in this study; A history of eradication of Helicobacter pylori; A recent history (last month)of antibiotic therapy in each patient or pregnancy

Age
No age limit

Gender
Both

Phase
1-2

Groups that have been masked
No information

Sample size
Target sample size: **321**

Randomization (investigator's opinion)
Randomized

Randomization description

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
Lorestan University of Medical Sciences

Street address
Deputy of Research and Technology,Integrated Paradise,Lorestan University of Medical Sciences,5 km Khorramabad- Tehran,Khorramabad

City
Khorramabad

Postal code

Approval date
2016-01-05, 1394/10/15

Ethics committee reference number
lums.REC.1394.49

Health conditions studied

1

Description of health condition studied
Helicobacter Pylori

ICD-10 code
B98.0

ICD-10 code description
Helicobacter pylori [H.pylori] as the cause of diseases classified to other chapters

Primary outcomes

1

Description
The eradication of Helicobacter pylori in group A

Timepoint
6week

Method of measurement
Carbon 13 urea breathing test

2

Description
Failure to eradicate Helicobacter pylori in group A

Timepoint
6 week

Method of measurement
Carbon 13 urea breathing test

3

Description
The eradication of Helicobacter pylori in group A

Timepoint
6 week

Method of measurement
Carbon 13 urea breathing test

4

Description
The eradication of Helicobacter pylori in group C

Timepoint
6 week

Method of measurement
Carbon 13 urea breathing test

5

Description
Failure to eradicate Helicobacter pylori in group B

Timepoint
6 week

Method of measurement
Carbon 13 urea breathing test

6

Description
Failure to eradicate Helicobacter pylori in group C

Timepoint
6 week

Method of measurement
Carbon 13 urea breathing test

Secondary outcomes

1

Description
The development of side effects of medications used in this study in any of the patients in Group A
Timepoint
6 week
Method of measurement
Patients’comments and examination by physician

2

Description
The development of side effects of medications used in this study in any of the patients in Group B
Timepoint
6 week
Method of measurement
Patients’comments and examination by physician

3

Description
The development of side effects of medications used in this study in any of the patients in Group C
Timepoint
6 week
Method of measurement
Patients’comments and examination by physician

Intervention groups

1

Description
The patients of Group C are placed under treatment for 7 days with the concomitant medication regimen.
Category
Treatment - Drugs

2

Description
The patients of groupA will be placed under treatment for 14 days with a classic medication regimen (including omeprazole (20 mg / b.i.d) plus amoxicillin (1000 mg / b.i.d) and clarithromycin (500 mg / b.i.d).
Category
Treatment - Drugs

3

Description
The patients of Group B are placed under treatment for 5 days with the concomitant medication regimen (including omeprazole (20 mg / bid) plus amoxicillin (1000 mg / bid), clarithromycin (500 mg / bid) and metronidazole (500 mg / BD).
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Rahimi Shahid Hospital
Full name of responsible person
Dr.Mosayab Moradniani
Street address
Department Of Internal , Rahimi Shihada Hospital, Khorramabad
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2

Recruitment center
Name of recruitment center
Shohada Ashayer Hospital
Full name of responsible person
Dr.Rouzbeh Yagoubi
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Department of Internal Medicine,Shohada Ashayer Hospital, Khorramabad
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Lorestan University of Medical Sciences
Full name of responsible person
Dr.Morovat Tahari Kalani
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Deputy of Research and Technology, Integrated Pardis, Lorestan University of Medical Sciences, Khorramabad
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Khorramabad
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Lorestan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Lorestan University Off Medical Sciences

Full name of responsible person
Rouzbeh Yaghubi

Position
Residency

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty