

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 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 intervention and 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

Name

Mosayeb Moradniani

Name of organization / entity

Lorestan University of Medical Sciences

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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

City

Khorramabad

2

Recruitment center

Name of recruitment center

Shohada Ashayer Hospital

Full name of responsible person

Dr.Rouzbeh Yagoubi

Street address

Department of Internal Medicine,Shohada Ashayer Hospital, Khorramabad

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Khorramabad

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

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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