

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of two Sequential therapy regimens and Standard Triple-Drug therapy for eradication of Helicobacter Pylori in patients with Dyspepsia

Protocol summary

Summary

The main objective of this study is to compare the effectiveness of two sequential therapy regimens versus standard triple-drug therapy for eradication of Helicobacter Pylori in patients suffering from Dyspepsia. This study is a randomized, not blinded, single-center, not placebo controlled trial. 300 patients with Dyspepsia who have the positive Helicobacter Pylori infection based on pathological result, after performing upper endoscopy, will be enrolled in the study. Patients that need more treatments based on endoscopy results, patients with severe underlying diseases, pregnant and lactating women and patients who have allergies to drugs we want to use are excluded. These 300 patients will be randomly divided into 3 equal groups using random numbers table. Each group contains 100 patients that are the same according to age and gender. Drug regimen for these groups is as below. Group 1 (intervention): Sequential therapy with Omeprazole, Amoxicillin, Clarithromycin and Metronidazole. Group 2 (intervention): Sequential therapy with Omeprazole, Amoxicillin, Levofloxacin and Metronidazole. Group 3 (control): Standard triple therapy with Omeprazole, Amoxicillin and Clarithromycin. Patients will be visited after the completion of treatment course to be asked about side effects of drugs and 6 weeks after the treatment, they will be analyzed with Urea Breath Test (UBT). Helicobacter Pylori eradication is based on the negativity of Urea Breath Test.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015082323736N1**

Registration date: **2016-02-09, 1394/11/20**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-02-09, 1394/11/20

Registrant information

Name

Mosayeb Moradniani

Name of organization / entity

Lorestan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 66 3333 6138

Email address

dr.m.morad@lums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Lorestan University of Medical Sciences

Expected recruitment start date

2016-01-05, 1394/10/15

Expected recruitment end date

2016-03-18, 1394/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of two Sequential therapy regimens and Standard Triple-Drug therapy for eradication of Helicobacter Pylori in patients with Dyspepsia

Public title

Efficacy of sequential therapy in eradication of Helicobacter Pylori

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with Dyspepsia for whom endoscopy was performed and those ones that have the positive Helicobacter Pylori infection based on pathology result and those who have not been treated for Helicobacter Pylori eradication before. Exclusion criteria: Patients that need more treatments based on endoscopy results, patients that have severe underlying diseases (heart disease, kidney disease, liver disease, etc), pregnant and lactating women, patients who have allergies to drugs we want to use.

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **300**

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

Ethics committee of Lorstan University of Medical Sciences

Street address

Lorestan University of Medical Sciences, Pardis campus, Kamalvand, Khorramabad, Lorestan

City

Khorramabad

Postal code

381251698

Approval date

2016-01-05, 1394/10/15

Ethics committee reference number

Lums.REC.1394.48

Health conditions studied

1

Description of health condition studied

Dyspepsia

ICD-10 code

K30

ICD-10 code description

Dyspepsia

2

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

Eradication of Helicobacter Pylori

Timepoint

6 weeks after the completion of treatment course

Method of measurement

(UBT) Urea Breath Test

Secondary outcomes

1

Description

Side effects of drugs

Timepoint

2 Weeks After Beginning of Treatment

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention 3 (Control group): Standard triple therapy with Omeprazole 20 mg capsule twice a day, Amoxicillin 1 g capsule twice a day and Clarithromycin 500 mg capsule twice a day for 2 weeks

Category

Treatment - Drugs

2

Description

Intervention 1: The sequential regimen is including Omeprazole 20 mg capsule twice a day and Amoxicillin 1 g capsule twice a day for the first week and Omeprazole 20 mg capsule twice a day, Clarithromycin 500 mg

capsule twice a day and Metronidazole 500 mg tablet twice a day for the second week

Category

Treatment - Drugs

3**Description**

Intervention 2: The sequential regimen is including Omeprazole 20 mg capsule twice a day and Amoxicillin 1 g capsule twice a day for the first week and Omeprazole 20 mg capsule twice a day, Levofloxacin 500 mg capsule twice a day and Metronidazole 500 mg tablet twice a day for the second week

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Khorramabad's Shohadaye Ashayer Hospital

Full name of responsible person

Mosayeb Moradniani, Gastroenterologist, Assistant professor

Street address

Khorramabad's Shohadaye Ashayer Hospital, Enghelab Blvd. Khorramabad, Lorestan

City

Khorramabad

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellor for research, Lorestan University of Medical Sciences

Full name of responsible person

Morovat Taheri Kalani

Street address

Lorestan University of Medical Sciences, Pardis campus, Kamalvand, Khorramabad, Lorestan

City

Khorramabad

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellor for research, 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**

Lorstan University of Medical Sciences

Full name of responsible person

Mosayeb Moradniani

Position

Gastroenterologist, Assistant professor

Other areas of specialty/work**Street address**

Lorestan University of Medical Sciences, Pardis campus, Kamalvand, Khorramabad, Lorestan

City

Khorramabad

Postal code

6819617691

Phone

+98 66 3341 1439

Fax**Email**

dr.m.morad@lums.ac.ir

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Lorstan University of Medical Sciences

Full name of responsible person

Mosayeb Moradniani

Position

Gastroenterologist, Assistant professor

Other areas of specialty/work**Street address**

Lorestan University of Medical Sciences, Pardis campus, Kamalvand, Khorramabad, Lorestan

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Fax**Email**

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Web page address**Person responsible for updating data****Contact****Name of organization / entity**

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campus, Kamalvand, Khorramabad, Lorestan

City

Khorramabad

Postal code

6819617691

Phone

+98 66 3341 1439

Fax**Email**

dr.m.morad@lums.ac.ir

Web page address**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