

# 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**

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**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*