# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 2026

## Comparison of the efficacy of 14- day high dose triple therapy regimen with 12-day concomitant quadreple therapy regimen on Helicobacter pylori eradication

## Protocol summary

**Study aim**

Comparison of the efficacy of 12-day concomitant and 14-day high-dose triple therapy on Helicobacter pylori eradication

**Design**

Phase 3 randomized clinical trial with control group, on 240 patients with Helicobacter pylori infection

**Settings and conduct**

In this randomized clinical trial, 240 patients with symptoms of indigestion referred to Tooba Gastroenterology Clinic and Imam Hospital in Sari city, Mazandaran province, after upper gastrointestinal endoscopy, will be included in the study, according to the inclusion and exclusion criteria. Randomization was performed according to the randomization table extracted from the internet.

**Participants/Inclusion and exclusion criteria**

Inclusion criteria was ages between 18 and 80 years who have H. pylori infection and have endoscopic findings of gastric ulcer or erosion, duodenal ulcer or duodenitis and or histologic evidence of intestinal metaplasia. Exclusion criteria: Pregnant or nursing women, those with a history of upper GI surgery, major cardiac, lung, liver or renal diseases, a history of previous H. pylori eradication regimen and history of known side effects to the protocol drugs would be excluded from the study.

**Intervention groups**

1- Control group that received the standard 4-drug regimen of PPI, amoxicillin, metronidazole, and clarithromycin. 2- Case group that received the high-dose 3-drug regimen of PPI, amoxicillin, and bismuth.

**Main outcome variables**

Success rate of this regimen in eradicating Helicobacter pylori, patient tolerance, drug side effects

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20131124015510N6**
Registration date: **2025-01-24, 1403/11/05**
Registration timing: **registered_while_recruiting**

Last update: **2025-01-24, 1403/11/05**
Update count: **0**

**Registration date**

2025-01-24, 1403/11/05

**Registrant information**

**Name**

Seyed Mohammad Valizadeh Toosi

**Name of organization / entity**

Mazandaran University Of Medical Sciences

**Country**

Iran (Islamic Republic of)

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**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2025-01-20, 1403/11/01

**Expected recruitment end date**

2025-06-21, 1404/03/31

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**
Comparison of the efficacy of 14- day high dose triple therapy regimen with 12-day concomitant quadreple therapy regimen on Helicobacter pylori eradication

**Public title**
Comparison of the efficacy quadreple therapy and triple therapy regimens on Helicobacter pylori eradication

**Purpose**
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
Inclusion criteria : ages between 18 and 80 years who have H. pylori positive and have endoscopic findings of gastric ulcer duodenal ulcer gastritis duodenitis histologic evidence of intestinal metaplasia.

**Exclusion criteria:**
Pregnant or nursing women, those with a history of upper GI surgery major cardiac diseases major lung diseases major liver diseases history of previous H. pylori eradication regimen history of known side effects to the protocol drugs major renal diseases

**Age**
From **18 years** old to **80 years** old

**Gender**
Both

**Phase**
3

**Groups that have been masked**

- Participant

**Sample size**
Target sample size: **240**
More than 1 sample in each individual
Number of samples in each individual: **1**
A person who has an indication for eradication therapy and receives the drug regimen and completes the study

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
First, we use a Random Number Generator to extract 240 random numbers from one to 240. These 240 extracted numbers include 1 and 2, which are arranged randomly and then the first number of patients are included in the study Number 1 receives the standard regimen and number 2 receives the study regimen.

**Blinding (investigator's opinion)**
Single blinded

**Blinding description**
Patients who include the the study would be blind. This means that the patient does not know whether she is receiving the 4-drug regimen or the high-dose 3-drug regimen.

**Placebo**
Not used

**Assignment**
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Ethics Committee of Imam Khomeini Hospital Educational and Medical Center

**Street address**
Amir mazandarani

**City**
Sari

**Province**
Mazandaran

**Postal code**
4815658681

**Approval date**
2025-01-06, 1403/10/17

**Ethics committee reference number**
IR.MAZUMS.IMAMHOSPITAL.REC.1403.083

## Health conditions studied

### 1

**Description of health condition studied**
Helicobacter Pylori Infection

**ICD-10 code**
B96.81

**ICD-10 code description**
Helicobacter pylori [H. pylori] as the cause of diseases classified elsewhere

## Primary outcomes

### 1

**Description**
Helicobacter pylori infection

**Timepoint**
Before the start of the Helicobacter pylori eradication regimen

**Method of measurement**
Through pathology before starting of Helicobacter pylori treatment regimen

## Secondary outcomes

### 1

**Description**
Helicobacter pylori eradication

**Timepoint**
8 weeks after end of HP eradication treatment

**Method of measurement**
Helicobacter pylori stool antigen test

## Intervention groups

### 1

**Description**
Intervention group: Patients receiving 14 days high-dose triple therapy of esomeprazole and amoxicillin & bismuth regimen for Helicobacter pylori eradication
**Category**
Treatment - Drugs

### 2

**Description**
Control group: Patients receiving a 12-day four-drug regimen for Helicobacter pylori eradication
**Category**
Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
کلینک طوبی شهرستان ساری
**Full name of responsible person**
محبوبه ابراهیمی
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### 2

**Recruitment center**
**Name of recruitment center**
Imam Khomeni Hospital
**Full name of responsible person**
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## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Mazandaran University of Medical Sciences
**Full name of responsible person**
دکتر احمد عنایتی
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Moallem street, Moallem Squre
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pajoheshi@mazums.ac.ir
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Mazandaran University of Medical Sciences
**Proportion provided by this source**
100
**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**
Mazandaran University of Medical Sciences
**Full name of responsible person**
Seyed Mohammad Valizadeh Toosi
**Position**
Associate Professor
**Latest degree**
Subspecialist
**Other areas of specialty/work**
Internal Medicine
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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**Web page address**

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available