

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Comparison of the efficacy of 14- day concomitant regimen with 14- day high dose esomeprazole and amoxicillin regimen on Helicobacter pylori eradication

Protocol summary

Study aim

Comparison of the efficacy of 14-day concomitant and 14-day high-dose dual 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, among patients with symptoms of dyspepsia referred to the gastroenterology clinic of Toba in Sari city in Mazandaran province, upper GI endoscopy was done. 240 patients, according to inclusion & exclusion criteria enrolled in the study. Randomization was according to random table generated from internet

Participants/Inclusion and exclusion criteria

Inclusion criteria were 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

Group receiving high doses of PPI and amoxicillin

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: **IRCT20131124015510N4**

Registration date: **2021-06-11, 1400/03/21**

Registration timing: **retrospective**

Last update: **2021-06-11, 1400/03/21**

Update count: **0**

Registration date

2021-06-11, 1400/03/21

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

2020-05-09, 1399/02/20

Expected recruitment end date

2021-05-10, 1400/02/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy of 14- day concomitant regimen with 14- day high dose esomeprazole and amoxicillin regimen on Helicobacter pylori eradication

Public title

Comparison of quadruple therapy and high dose dual therapy on Helicobacter pylori eradication

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Inclusion criteria was ages between 18 and 80 years who have H. pylori positive 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.

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**

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

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Mazandaran University of Medical Sciences

Street address

moallem

City

Sari

Province

Mazandaran

Postal code

4816633131

Approval date

2020-04-22, 1399/02/03

Ethics committee reference number

IR.MAZUMS.IMAMHOSPITAL.REC.1399.7090

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

In the beginning of the study when patient enrolled the study

Method of measurement

Evaluation of Helicobacter pylori infection by RUT test or pathology

Secondary outcomes**1****Description**

Helicobacter pylori eradication

Timepoint

Six to 8 weeks after end of HP eradication treatment

Method of measurement

H pylori stool antigen test

Intervention groups**1****Description**

Control group: Patients receiving the standard 14-day Helicobacter pylori eradication regimen

Category

Treatment - Drugs

2**Description**

Intervention group: Patients receiving 14 days high-dose

PPI and amoxicillin regimens for Helicobacter pylori eradication

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Toba clinic of Sari city

Full name of responsible person

Seyed Mohammad Valizadeh Toosi

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Khazar bolvard

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr sayedi

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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

Assistant Professor Mazandaran University of Medical Sciences

Latest degree

Subspecialist

Other areas of specialty/work

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Latest degree

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Person responsible for updating data

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Latest degree

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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

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable