

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Comparison of the efficacy of 14-days high dose dual therapy and 14 days concomitant regimens as first line regimen for Helicobacter pylori eradication

Protocol summary

Study aim

Comparison of the effectiveness of a 14-day simultaneous diet with a 14-day high-dose diet of esomeprazole and amoxicillin on eradication of Helicobacter pylori

Design

Phase 3 randomized clinical trial with control group, on 210 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. 210 patients, according to inclusion & exclusion criteria enrolled in the study. Randomization according to random table was extracted from 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

The group receiving the high-dose two-drugs regimen of PPI and amoxicillin as the intervention group and the group receiving the concomitant quadruple therapy as the control group are included in the study.

Main outcome variables

Helicobacter pylori eradication rate, patient tolerance, drug side effects

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20131124015510N5**

Registration date: **2022-05-27, 1401/03/06**

Registration timing: **registered_while_recruiting**

Last update: **2022-05-27, 1401/03/06**

Update count: **0**

Registration date

2022-05-27, 1401/03/06

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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+98 11 3320 2242

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-22, 1401/03/01

Expected recruitment end date

2022-09-22, 1401/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of the efficacy of 14-days high dose dual therapy and 14 days concomitant regimens as first line regimen for Helicobacter pylori eradication

Public title
Evaluation of the effectiveness of two- and four-drugs regimens in eradication of H pylori

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 People with peptic ulcer or gastro-duodenal erosion
 Helicobacter pylori infection on a pathological biopsy or
 Rapid urease test who have not previously received a
 Helicobacter pylori eradication regimen
Exclusion criteria:
 Age under 18 years Pregnancy and lactation
 Concomitant use of anticoagulants, corticosteroids or
 ketoconazole atients who have a history of gastric
 surgery Patients with a confirmed history of severe heart
 or lung failure, chronic kidney failure, chronic liver
 disease or a history of cancer. History of drug allergy to
 the drugs of this study Previous history of Helicobacter
 pylori eradication

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

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **210**

Randomization (investigator's opinion)
Randomized

Randomization description
By using a Random Number Generator from web site of <https://stattrek.com/statistics/random-number-generator.aspx> , patients are randomly divided into two groups. First, I extract random numbers from the internet Equal to the number of patients to be included in the study. For example, in our study, 210 patients should be included in the study. First, a random number table is extracted from the Internet to the number of people entering the study, then, for example, number of one are assigned to the concomitant qudreple therapy group and two are assigned to the high-dose dual therapy regimen, and thus patients become random.

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 Mazandaran University of Medical Sciences

Street address

Imam Khomeini Hospital, Amir Mazandarani Ave.

City

Sari

Province

Mazandaran

Postal code

4816633131

Approval date

2022-03-16, 1400/12/25

Ethics committee reference number

IR.MAZUMS.IMAMHOSPITALREC.1400.10588

Health conditions studied

1

Description of health condition studied

Peptic ulcer disease and H pylori infection

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

Helicobacter pylori infection rat

Timepoint

Evaluation of Helicobacter pylori infection at the beginning of the study and then 8 weeks after receiving the desired treatment regimen

Method of measurement

Measurement of Helicobacter pylori infection variable by pathology at the beginning of the study and confirmation of eradication at the end of the study by fecal antigen method

Secondary outcomes

1

Description

H pylori infection eradication

Timepoint

initiation of study and 8 weeks after end of treatment

Method of measurement

At the beginning of treatment by pathology and at the end of treatment by fecal antigen of *Helicobacter pylori*

Intervention groups

1

Description

Intervention group: In this study, patients in the intervention group used esomeprazole capsules 40 mg three times a day and amoxicillin 500 mg capsules three times a day for 14 days.

Category

Treatment - Other

2

Description

Control group: In the control group, patients take esomeprazole 40 mg, amoxicillin 500 mg, metronidazole 500 mg and clarithromycin 500 mg one every 12 hours for 14 days.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Toba Clinic

Full name of responsible person

Seyed Mohammad Valizadeh Toosi

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Khazar Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr Majed Saeedi

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Web page address

<https://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

Assistant Professor,

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Position

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Person responsible for updating data

Contact

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Mazandaran University of Medical Sciences
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

no more information.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

patients symptoms and H pylori infection status

When the data will become available and for how long

End of study

To whom data/document is available

Chief study designer

Under which criteria data/document could be used

Study publishing

From where data/document is obtainable

Chief study designer

What processes are involved for a request to access data/document

Contact with chief study designer

Comments