Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 esmoprazole and emoxicillin 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, accoeding to inclusion & exclusion criteria enrolad the study. randomization are according to random table was extracted from internet

Participants/Inclusion and exclusion criteria

nclusion 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 quadreple therapy as the control group are included in the study.

Main outcome variables

Helicobacter pylori eradication rat, 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)

Phone

+98 11 3320 2242

Email address

sm.valizadehtoosi@mazums.ac.ir

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 esmoprazole 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 esmoprazole 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
Street address
Khazar Blvd
City
Sari
Province
Mazandaran
Postal code
4818911915
Phone
+98 11 3320 2242
Email
seyedmohammadv@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Dr Majed Saeedi
Street address
Moallem Ave
City
Sari
Province
Mazandaran
Postal code
4815733971
Phone
+98 11 3326 1244
Email
pajoheshi@mazums.ac.ir
Web page address
https://pajooheshi.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
Street address
Amire Mazandarani Ave
City
Sari
Province
Mazandaran
Postal code
4816633131
Phone
+98 11 3335 0672
Email
seyedmohammadv@yahoo.com

Person responsible for scientific 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

Street address
Amir Maznandarani Ave

City
Sari

Province
Mazandaran

Postal code
4816633131

Phone
+98 11 3335 0670

Email
seyedmohammadv@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Mazandaran University of Medical Sciences

Full name of responsible person
Seyed Mohamad Valizadeh Toosi

Position
Assistant Professor Mazandaran University of Medical Sciences

Latest degree
Subspecialist

Other areas of specialty/work
Internal Medicine

Street address
Amir mazandarani,

City
Sari

Province
Mazandaran

Postal code
4816633131

Phone
+98 11 3335 0670

Email
seyedmohammadv@yahoo.com

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 desginer

Under which criteria data/document could be used
Study publishing

From where data/document is obtainable
Chief study desginer

What processes are involved for a request to access data/document
Contact with chief study desginer

Comments