Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of the efficacy of 10-day vs. 12-day concomitant therapies for first-line Helicobacter pylori eradication in Iran.

Protocol summary

Study aim
Evaluation and comparison of the efficacy of 10-day versus 12-day concomitant therapy as the first-line treatment for H. pylori eradication in Iran.

Design
This is a randomized single-blind clinical trial with a control group. In this study, Two hundred patients with peptic ulcer disease and Helicobacter pylori infection who refer to Gastroenterology clinic of Imam Khomeini hospital of Sari, will enter the study. They will be divided into 2 groups with block randomization method. The first group will receive 10-ay and the second group will recieve 12-day concomitant regimen. Eight weeks after therapy, Helicobacter pylori eradication will be assessed by Urea breath test.

Settings and conduct
This is a single blind study, performed on 200 patients with peptic ulcer disease and Helicobacter pylori infection in Gastroenterology clinic of Imam Khomeini hospital of Sari. These patients are divided into 2 groups by block randomization method and then will be treated by either 10-day or 12-day concomitant regimen.

Participants/Inclusion and exclusion criteria
Two hundred patients with peptic ulcer disease and Helicobacter pylori infection according to pathologic assessment of gastric biopsy or rapid urease test, and no history of previous treatment for Helicobacter pylori eradication, will enter the study.

Intervention groups
The first group will receive 10-ay and the second group will recieve 12-day concomitant regimen composed of Pantoprazole 40 mg, Amoxicillin 1000 mg, Clarithromycin 500 mg and Metronidazole 500 mg, all given twice daily.

Main outcome variables
Helicobacter pylori eradication status

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170521034070N2**
Registration date: **2019-10-28, 1398/08/06**
Registration timing: **retrospective**

Last update: **2019-10-28, 1398/08/06**
Update count: **0**

Registration date
2019-10-28, 1398/08/06

Registrant information
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Zohreh Bari
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-12-22, 1397/10/01

Expected recruitment end date
2019-09-22, 1398/06/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the efficacy of 10-day vs. 12-day concomitant therapies for first-line Helicobacter pylori

eradication in Iran.

Public title
Concomitant therapies for first-line Helicobacter pylori eradication
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with peptic ulcer disease according to endoscopic findings Presence of Helicobacter pylori is proven in gastric tissue according to pathologic assessment of gastric biopsy No history of previous treatment for Helicobacter pylori
Exclusion criteria:
Breast feeding History of gastrointestinal surgery History of gastrointestinal malignancy using anticoagulant drugs using anti convulsion drugs pregnancy
Age
From **18 years** old to **80 years** old
Gender
Both

Phase
3
Groups that have been masked

- Data analyser

Sample size
Target sample size: **200**
Randomization (investigator's opinion)
Randomized
Randomization description
Block randomization was used. So that patients were classified in 5-patients blocks according to their age and gender and the first five patients will enter the 10-day regimen group and the next five patients will enter the 12-day regimen group and this classification will be continued respectively until the total number of cases would be completed.
Blinding (investigator's opinion)
Single blinded
Blinding description
The statistician is blind to the study groups.
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
Amir Mazandarani street
City
Sari
Province
Mazandaran
Postal code
4816613135
Approval date
2018-06-11, 1397/03/21
Ethics committee reference number
IR.MAZUMS.IMAMHOSPITAL.REC.1397.031

Health conditions studied

1

Description of health condition studied
Gastric ulcer
ICD-10 code
K25
ICD-10 code description
Gastric ulcer

2

Description of health condition studied
Duodenal ulcer
ICD-10 code
K26
ICD-10 code description
Duodenal ulcer

Primary outcomes

1

Description
Helicobacter pylori eradication
Timepoint
Eight weeks after receiving the drugs, Helicobacter pylori eradication will be evaluated by Urea Breath test.
Method of measurement
Urea Breath test.

Secondary outcomes

empty

Intervention groups

1

Description
Patients in the intervention group will receive Pantoprazole 40 mg, Amoxicillin 1g, Clarithromycin 500 mg and Metronidazole 500 mg (all given twice daily) for ten days.
Category
Treatment - Drugs

2

Description
Patients in the control group will receive Pantoprazole 40 mg, Amoxicillin 1g, Clarithromycin 500 mg and Metronidazole 500 mg (all given twice daily) for twelve days.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Zohreh Bari
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Dr. Majid Saeidi
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Moallem square
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4817844718
Phone
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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
Sari 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
Zohreh Bari
Position
Assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
Gastroenterology and hepatology
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

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

Data Dictionary
Not applicable

Title and more details about the data/document
The results of this study about Helicobacter pylori eradication rate will be published after deidentification of the participants.

When the data will become available and for how long
immediately after being published

To whom data/document is available
There is no limitation.

Under which criteria data/document could be used
There is no limitation.

From where data/document is obtainable
There is no limitation.

What processes are involved for a request to access data/document
It will be according to guidelines of the journal that will publish the article derived from the results of this study.

Comments