Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of the effect of Sequential Therapy and Triple Therapy for Helicobacter Pylori Eradication

Protocol summary

Study aim
Comparison of the effect of Sequential Therapy and Triple Therapy for Helicobacter Pylori Eradication

Design
In this study, 144 patients with H.pylori infection will undergo gastroscopy if they meet all the inclusion criteria and none of the exclusion criteria. A written consent will be received from all patients before participating in the study and undergoing esophago-gastro-duodenoscopy. Then they will randomly be divided into the sequential therapy and standard triple therapy groups by tossing coin.

Settings and conduct
This is a double blinded clinical trial on patients who refer to Shahid Mohammadi Hospital in Bandar Abbas. Patients will be divided randomly into sequential therapy and standard triple therapy groups. Information about the type of treatment will be kept secret from the patients, pathologists, and physicians involved in the treatment. For this purpose, the drugs given to each group will be placed in the same package alongside the instructions.

Participants/Inclusion and exclusion criteria
Inclusion criteria: No history of H. pylori treatment, age above 18, Gastrointestinal symptoms like nausea, vomiting, indigestion, and melena, Being a candidate for endoscopy, Not responding to experimental therapy
Exclusion criteria: Pregnancy, Lactating, severe Heart, Liver, Lung, or Kidney diseases, having malignancies, Being allergic to amoxicillin, clarithromycin, or tinidazole

Intervention groups
Intervention group 1: Patients in sequential therapy group received pantoprazole 20 mg twice daily for 10 days, amoxicillin 1000 mg twice daily for the first 5-day period followed by tinidazole 500 mg twice daily for the second 5-day period. Intervention group 2: Patients in standard triple therapy group, received pantoprazole 20 mg, clarithromycin 500 mg, and amoxicillin 1000 mg (all medicines twice daily) for 14 days.

Main outcome variables
H-Pylori infection eradication rate

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20180131038581N2**
Registration date: **2018-07-05, 1397/04/14**
Registration timing: **registered_while_recruiting**

Last update: **2018-07-05, 1397/04/14**
Update count: **0**

Registration date
2018-07-05, 1397/04/14

Registrant information
Name
Hamid Mousavi
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 76 3333 3280
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h.mousavi@hums.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-06-22, 1397/04/01
Expected recruitment end date
2018-08-23, 1397/06/01
Actual recruitment start date
empty
Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of Sequential Therapy and Triple Therapy for Helicobacter Pylori Eradication

Public title
Investigating the effect of Sequential Therapy and Triple Therapy for H-pylori treatment

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients who had not previously been treated for H. pylori Being older than 18 years Gastrointestinal symptoms such as nausea, vomiting, indigestion and melena Being a candidate for endoscopy Not responding to experimental therapy

Exclusion criteria:
Pregnant patients Lactating patients Patients with severe heart Liver disease Lung disease Kidney disease Patients with malignancies Being allergic to amoxicillin Being allergic to clarithromycin Being allergic to tinidazole Patient's dissatisfaction with participating in the study

Age
From **18 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size
Target sample size: **144**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, patients with gastrointestinal symptoms such as nausea, vomiting, indigestion and melena, who did not respond to experimental therapy and who were candidates for endoscopy, were included in the study. Patients were randomly divided into two groups of sequential therapy and standard triple therapy by tossing a coin.

Blinding (investigator's opinion)
Double blinded

Blinding description
Information about the type of treatment will be kept secret from the patients, pathologists, and physicians involved in the treatment. For this purpose, the drugs of each group will be placed in the same package alongside the instructions and will be given to the patients.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics commitee of Hormozagan University of Medical Sciences

Street address
Shahid Chamran Blvd.

City
Bandar Abbas

Province
Hormozgan

Postal code
7916613885

Approval date
2018-01-06, 1396/10/16

Ethics committee reference number
HUMS.REC.1396.123

Health conditions studied

1

Description of health condition studied
Helicobacter Pylori

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 eradication rate

Timepoint
4 weeks after the completion of treatment

Method of measurement
Urea breath test (UBT)

Secondary outcomes

1

Description
Mild drug side effects

Timepoint
4 weeks after the completion of treatment

Method of measurement
Questionnaire, Physician's examination of patient's clinical symptoms

2

Description
Severe drug side effects
Timepoint
4 weeks after the completion of treatment
Method of measurement
Questionnaire, Physician's examination of patient's clinical symptoms

3

Description
Drug intolerance
Timepoint
4 weeks after the completion of treatment
Method of measurement
Questionnaire, Physician's examination of patient's clinical symptoms

Intervention groups

1

Description
Intervention group 1: Patients in sequential therapy group received pantoprazole 20 mg twice daily for 10 days, amoxicillin 1000 mg twice daily for the first 5-day period followed by tinidazole 500 mg twice daily for the second 5-day period.
Category
Treatment - Drugs

2

Description
Intervention group 2: Patients in standard triple therapy group, received pantoprazole 20 mg, clarithromycin 500 mg, and amoxicillin 1000 mg (all medicines twice daily) for 14 days.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Mohammadi Hospital of Bandar Abbas
Full name of responsible person
Hamid Mousavi
Street address
Islamic Republic of Iran Blvd.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bandare-abbas University of Medical Sciences
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Hamid Mousavi
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Grant name
Vice chancellor of research, Hormozgan University of Medical Sciences
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Bandar Abbas 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
Bandare-abbas University of Medical Sciences
Full name of responsible person
Hamid Mousavi
Position
Associate professor
Latest degree

Subspecialist
Other areas of specialty/work
Hepatology and Gastroentrology
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Person responsible for updating data

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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
There is no further 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
No - There is not 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