

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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)

Phone

+98 76 3333 3280

Email address

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 committee 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

Full name of responsible person

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 Gastroenterology

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Person responsible for scientific inquiries

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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