

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Sequential Therapy versus Quadruple Therapy for Helicobacter pylori Eradication

Protocol summary

Study aim

Sequential Therapy versus Quadruple Therapy for Helicobacter pylori Eradication

Design

Clinical trial, with parallel groups, randomized, phase 3 on 174 patients. Excel software rand function is used for randomization.

Settings and conduct

Patients referred to the gastrointestinal clinic of Al-zahra Hospital who have upper gastrointestinal symptoms such as epigastric pain, anorexia, nausea and pain with eating, premature satiety, belching, etc. and after initial examination (liver, biliary and pancreatic problems) Undergo upper endoscopy. also The urease test is used to prove Helicobacter pylori infection. Patients in the first group are treated with 4 drugs and the second group is treated consecutively, followed by tinidazole, clarithromycin and PPI for 5 days. Patients' symptoms are assessed by the SF-LDQ questionnaire before and after treatment. Helicobacter pylori infection is confirmed by a stool antigen test.

Participants/Inclusion and exclusion criteria

Inclusion: Age 18 years and older Ulcerative peptic ulcer disease based on upper gastrointestinal endoscopy
Exclusion: Having any of the following diseases: MALT, Zollinger-Ellison syndrome, various types of gastrointestinal cancers, liver or kidney diseases, other infections that require antibiotics, immunodeficiency diseases. History of upper gastrointestinal surgery
History of Helicobacter pylori eradication or history of Proton pump inhibitor (PPI) use of antibiotics or probiotics (artificial or natural) during the past 4 weeks

Intervention groups

1) group receiving quadruple diet with PPI + bismuth + amoxicillin + metronidazole for 14 days and 2) group receiving sequential diet including PPI and amoxicillin for 5 days and then PPI And clarithromycin and tinidazole for 5 days.

Main outcome variables

Incidence rate; Duration of treatment; Helicobacter pylori eradication rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171230038142N20**

Registration date: **2020-09-19, 1399/06/29**

Registration timing: **registered_while_recruiting**

Last update: **2020-09-19, 1399/06/29**

Update count: **0**

Registration date

2020-09-19, 1399/06/29

Registrant information

Name

Khosro Tavakol

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 9134

Email address

tavakol@nm.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-22, 1399/05/01

Expected recruitment end date

2020-10-06, 1399/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Sequential Therapy versus Quadruple Therapy for Helicobacter pylori Eradication

Public title

Sequential Therapy versus Quadruple Therapy for Helicobacter pylori Eradication

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age 18 years and older Ulcerative peptic ulcer disease based on upper gastrointestinal endoscopy

Exclusion criteria:

Having any of the following diseases: MALT, Zollinger-Ellison syndrome, various types of gastrointestinal cancers, liver or kidney diseases, other infections that require antibiotics, immunodeficiency diseases. History of upper gastrointestinal surgery History of Helicobacter pylori eradication or history of PPI use of antibiotics or probiotics (artificial or natural) during the past 4 weeks

AgeFrom **18 years** old**Gender**

Both

Phase

3

Groups that have been masked*No information***Sample size**Target sample size: **174****Randomization (investigator's opinion)**

Randomized

Randomization description

At first, the samples are selected in an accessible manner, according to the entry and exit criteria, from the patients referred to the gastrointestinal clinic of Al-Zahra Hospital in Isfahan. Then, for allocation to two groups of quadruple and sequential, the selected patients are allocated to blocks with a volume of 4 by block random allocation method. In this way, blocks of volume 4, are formed based on the variables of sex and weight, and then within each block, half of the people in the quadruple group and half of the people in the sequential group are included, in order to maintain the balance of the number of participants in each group. In this study, 42 quadruple blocks and one hexagonal block were considered and the method of allocating samples was randomly substituted so that if heterogeneity in terms of matched groupings is observed in the final result, by creating a random sequence, the samples are again repeat and corrected.

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 Isfahan University of Medical Sciences

Street address

Hezar Jarib Ave., Isfahan University of Medical Sciences.

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Approval date

2020-06-28, 1399/04/08

Ethics committee reference number

IR.MUI.MED.REC.1399.264

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**

The incidence of complications

Timepoint

Days 15 and 30 after starting treatment

Method of measurement

Question from the patient

2**Description**

Duration of treatment

Timepoint

After treatment

Method of measurement

Counting the days of receiving treatment

3

Description

Helicobacter pylori eradication rate

Timepoint

After treatment

Method of measurement

Stool test

4

Description

Patient symptoms

Timepoint

Before and after treatment

Method of measurement

SF-LDQ questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:quadruple group: 87 patients with Helicobacter pylori infection who were indicated for treatment were selected. They then received a quadruple diet with PPI + bismuth + amoxicillin + metronidazole for 14 days. The drugs are made by Sobhan Company from Iran.

Category

Treatment - Drugs

2

Description

Intervention group: sequential group: 87 patients with Helicobacter pylori infection who were indicated for treatment were selected. They will then receive a sequential diet, including PPI and amoxicillin for 5 days, followed by PPI and clarithromycin and tinidazole for 5 days. The drugs are made by Sobhan Company from Iran.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra Hospital in Isfahan

Full name of responsible person

Atusa Hakami Fafd

Street address

Al Zahra Hospital, Sufeh Street.

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81747-73461

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+98 31 3668 0048

Email

a.hakamifard@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Hagjoo Javakmard

Street address

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Atusa Hakami Fafd

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Infectious diseases

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Atusa Hakami Fafd

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Infectious diseases

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Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Neda Abrishami

Position

Researcher

Latest degree

Master

Other areas of specialty/work

Biostatistics

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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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Information will be provided to applicants after anonymity and one year after the publication of the results.

When the data will become available and for how long

one year after the publication of the results

To whom data/document is available

Doctors, infectious disease specialists

Under which criteria data/document could be used

Comparison of current drug regimens with other regimens

From where data/document is obtainable

Send email to a.hakamifard@gmail.com

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

Send email to a.hakamifard@gmail.com

Comments