Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

Age
From **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
Isfehan

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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Shaghayegh Hagjoo Javakmard
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Isfehan
Postal code
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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 updating data

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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