Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jun 2026

Comparison of three therapeutic regimens (Rabiprazole, Amoxicillin, Bismuth subcetate, Clarithromycin (1), Rabiprazole, Amoxicillin, Clarithromycin (2) Rabiprazole, Amoxicillin, Bismuth subcetate, Furazolidone (3)) in eradication of Helicobacter pylori in

Protocol summary

Study aim

The objective of this open-label randomized clinical trial is compare of three therapeutic regimens (Rabiprazole, Amoxicillin, Bismuth subcitrate, Clarithromycin (A), Rabiprazole, Amoxicillin, Clarithromycin (B), Rabiprazole, Amoxicillin, Bismuth subcetate, Furazolidone (C)) in eradication of Helicobacter pylori in patients with dyspepsia. In this study, the effect of adding Bismuth subcitrate to the treatment regimen of Clarithromycin, Amoxicillin and Rabiprazole will also be evaluated.

Design

In this research, 90 patients with dyspepsia and Helicobacter pylori infection will be included in the study. Inclusion criteria is endoscopic and biopsied patients; report of the Helicobacter pylori organism in the tissue sample. Exclusion criteria is pregnancy; intolerance to drugs; interaction with medications such as digoxin; drug complications during treatment. The subjects will randomly divided into three groups and each group is randomly treated with one of the three therapeutic regimens.

Settings and conduct

In this open-label randomized clinical trial, 90 patients with dyspepsia and Helicobacter pylori infection will be included in the study. The subjects will randomly divided into three groups and each group is randomly treated with one of the three therapeutic regimens. Intervention will be done in three groups: Rabiprazole for 6 weeks, Amoxicillin, Bismuth subcitrate and Clarithromycin for 2 weeks (A), Rabiprazole for 6 week, Amoxicillin and Clarithromycin for 2 weeks (B), Rabiprazole for 6 weeks, Amoxicillin, Bismuth subcetate and Furazolidone for 2 weeks (C). Demographic information, history of smoking, alcohol consumption, previous upper gastrointestinal bleeding, inflammation of the tissue in the pathology report and endoscopic findings will recorded questionnaires. The fecal antigen of the Helicobacter pylori will checked four weeks after the end of the treatment. Then the collected data will be analyzed.

Participants/Inclusion and exclusion criteria

Inclusion criteria is endoscopic and biopsied patients; report of the Helicobacter pylori organism in the tissue sample.

Intervention groups

Intervention will be done in three groups: Rabiprazole for 6 weeks, Amoxicillin, Bismuth subcitrate and Clarithromycin for 2 weeks (A), Rabiprazole for 6 week, Amoxicillin and Clarithromycin for 2 weeks (B), Rabiprazole for 6 weeks, Amoxicillin, Bismuth subcetate and Furazolidone for 2 weeks (C).

Main outcome variables

The fecal antigen of the Helicobacter pylori will checked four weeks after the end of the treatment.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160318027097N6**
Registration date: **2017-12-12, 1396/09/21**
Registration timing: **prospective**

Last update: **2017-12-12, 1396/09/21**
Update count: **0**

Registration date

2017-12-12, 1396/09/21

Registrant information

Name

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Name of organization / entity

Country

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Ardebil University of Medical Sciences

Expected recruitment start date

2017-12-16, 1396/09/25

Expected recruitment end date

2018-03-16, 1396/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of three therapeutic regimens (Rabiprazole, Amoxicillin, Bismuth subcetate, Clarithromycin (1), Rabiprazole, Amoxicillin, Clarithromycin (2) Rabiprazole, Amoxicillin, Bismuth subcetate, Furazolidone (3)) in eradication of Helicobacter pylori in

Public title

Treatment of Helicobacter Pylori infection in patients with dyspepsia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Endoscopic and biopsied patients; Report of the Helicobacter pylori organism in the tissue sample.

Exclusion criteria:

Pregnancy; Intolerance to drugs; Interaction with medications such as digoxin; drug complications during treatment.

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization is block, individual and using a random number table in this study. 90 numbers will entered the random block and numbers are randomly assigned into three groups. Accordingly, the patients will receive one of three regimens with their randomly assigned number. In this study, participants, researchers are unaware of prescription drugs.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

90 numbers will enter the random block, and randomly the numbers are divided into three groups. Accordingly, patients will receive one of three regimens with their randomly pre-assigned number.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ardebil University of Medical Sciences

Street address

Ardebil University of Medical Sciences, daneshghah ave, Ardebil, Iran

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5163639888

Approval date

2017-07-24, 1396/05/02

Ethics committee reference number

IR.ARUMS.REC.1396.85

Health conditions studied

1

Description of health condition studied

Dyspepsia

ICD-10 code

K30

ICD-10 code description

Dyspepsia

Primary outcomes

1

Description

fecal antigen of Helicobacter pylori

Timepoint

4 weeks after Intervention

Method of measurement

ELISA

Secondary outcomes

empty

Intervention groups

1

Description
Case group (2): Rabiprazole, Tablet 40mg oral OD for 6 weeks. Amoxicillin, Tablet 1000mg oral BD for 2 weeks. Clarithromycin, Tablet 500mg oral BD for 2 weeks
Category
Treatment - Drugs

2

Description
Case group (3): Rabiprazole, Tablet 40mg oral OD for 6 weeks. Amoxicillin, Tablet 1000mg oral BD for 2 weeks. Bismuth subcitrate, Tablet 120mg oral BD for 2 weeks. Furazolidone Tablet 200mg oral BD for 2 weeks
Category
Treatment - Drugs

3

Description
Case group (1): Rabiprazole, Tablet 40mg oral OD for 6 weeks. Amoxicillin, Tablet 1000mg oral BD for 2 weeks. Bismuth subcitrate, Tablet 120mg oral BD for 2 weeks. Clarithromycin Tablet 500mg oral BD for 2 weeks
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Vice Chancellor for research of Ardebil University of Medical Sciences
Full name of responsible person
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Sponsors / Funding sources

1

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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
Vice Chancellor for research of Ardebil 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
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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
Total potential data after unidentifiable individuals
When the data will become available and for how long
Start the access period from 2019
To whom data/document is available
Researchers in academic and scientific institutions
Under which criteria data/document could be used
Data can be used for scientific and research studies.
From where data/document is obtainable
Dr Masoud Tasoji; Internal Medicine Assistant; M.tasoji@arums.ac.ir
What processes are involved for a request to access data/document
After receiving the request email, data files will be sent in less than a week.
Comments