Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jul 2026

Comparing success rate of three antibiotic regimes based on furazolidone, clarithromycine and levofluxacin in patients with Helicobacter pylori

Protocol summary

Summary

Objectives: The purpose of this study is to compare success rate of H.pylori eradication between 3 antibiotic regimes. Major inclusion criteria and exclusion criteria: Patients with dyspepsia and Peptic ulcer disease were included. Patients with history of taking antibiotic in last 3 weeks, gastrointestinal bleeding, gastric cancer and taking PPI or H2 receptor antagonists in the last two week were excluded. Design: This study will be conducted on 90 patients who referred to Gastroenterology Clinic in Qazvin province. Setting and conduct: Following the confirmation of H.pylori with Rapid urease test and randomization (balanced block randomization) they will be divided to 3 groups which each group will receive one of the following three regimens for a two-week period: Intervention: First group: Tab Pantoprazole 40 mg bd /Cap Amoxicillin 1000 mg bd / Tab Clarithromycin 500 mg bd. Second group: Pantoprazole 40 mg bd/Cap Amoxicillin 1000 mg bd/Tab Levofloxacin 500 mg daily. Third group: Tab Pantoprazole 40 mg bd/Cap Amoxicillin 1000 mg bd /Tab Furazolidone 100 mg bd. Main outcome variables: Three weeks after the termination of treatment, H. pylori stool antigen test will be checked for all patients to confirm eradication of H. pylori.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016040318124N4**
Registration date: **2017-10-07, 1396/07/15**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-10-07, 1396/07/15

Registrant information

Name

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Name of organization / entity

Metabolic Diseases Research Center, Qazvin University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2017-07-23, 1396/05/01

Expected recruitment end date

2017-10-23, 1396/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing success rate of three antibiotic regimes based on furazolidone, clarithromycine and levofluxacin in patients with Helicobacter pylori

Public title

Comparing success rate of three antibiotic regimes based on furazolidone, clarithromycine and levofluxacin in patients with gastric infection

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Patients aged 15 to 80 years; patients with dyspepsia and Peptic ulcer disease; Patients undergoing upper endoscopic procedure with positive rapid urease test (RUT). Exclusion criteria: gastrointestinal bleeding; Patients with history of taking antibiotic in last 3 weeks; taking PPI or H2 receptor antagonists in the last two week; gastric cancer; suffering from any disease needing to consume another antibiotic
Age
From **15 years** old to **80 years** old
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
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
balanced block randomization

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of the Qazvin University of Medical Sciences
Street address
Qazvin, Shahid Bahonar Blvd
City
Qazvin
Postal code
Approval date
2017-04-08, 1396/01/19
Ethics committee reference number
IR.QUMS.REC.1396.62

Health conditions studied

1

Description of health condition studied
Helicobacter pylori
ICD-10 code
B98
ICD-10 code description
Helicobacter pylori [H.pylori] as the cause of diseases classified to other chapters

Primary outcomes

1

Description
Helicobacter pylori eradication
Timepoint
2 week after treatment
Method of measurement
Stool antigen test

Secondary outcomes

1

Description
Drug reaction
Timepoint
During treatment
Method of measurement
Questioner

Intervention groups

1

Description
First group: Tab Pantoprazole 40 mg bd /Cap Amoxicillin 1000 mg bd / Tab Clarithromycin 500 mg bd.
Category
Treatment - Drugs

2

Description
Second group: Pantoprazole 40 mg bd/Cap Amoxicillin 1000 mg bd/Tab Levofloxacin 500 mg daily
Category
Treatment - Drugs

3

Description
Third group: Tab Pantoprazole 40 mg bd/Cap Amoxicillin 1000 mg bd /Tab Furazolidone 100 mg bd
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Velayat educational and treatment center
Full name of responsible person
Dr. Aliakbar Hajiaghamohammadi
Street address
City
Qazvin

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Investigator
Full name of responsible person
-
Street address
-
City
Qazvin
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Investigator
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary

empty