Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparision of two quadriple regimen amoxicillin, bismuth subsalicylate, pantoprazole, clarythromycin and amoxicillin, bismuth subsalicylate, pantoprazole, gemifloxacin in eradication of H.pylori infection

Protocol summary

Summary

Comparision of two quadriple regimen amoxicillin, bismuth subsalicylate, pantoprazole, clarythromycin and amoxicillin, bismuth subsalicylate, pantoprazole, gemifloxacin in eradication of H.pylori infection. This study is a randomized clinical trial in new patients with H.pylori infection. Inclusion criteria: New cases of H.pylori infection; patients between 18 to 80 years old Exclusion criteria: The pregnant and brest feeding women; gastric and esophagial malignancies; pylor stenosis; iiver cirrhosis; opium addicts; hypersensitivity to amoxicillin; bismuth subsalicylate; pantoprazole; clarythromycin; gemifloxacin; using cholestyramine; renal failure; history of sizzure; favism and hematologic disorders; incomplete treatment (under 80%); consent to continue treatment; history of H.pylori treatment. One hundred eighty two patients divided to two groups. One group treated with cap amoxicillin 500 miligram two numbers every 12 hours, tab bismuth subsalicylate 120 miligram two numbers every 12 hours, tab pantoprazole 20 miligram one number daily, tab clarythromycin 500 miligram one number every 12 hours and the other group treated with cap amoxicillin 500 miligram two numbers every 12 hours, tab bismuth subsalicylate 120 miligram two numbers every 12 hours, tab pantoprazole 20 miligram one number daily, tab gemifloxacin 320 miligram one number daily for 10 days period. Eight to twelve weeks after completion of treatment, all of patients assessed about eradication of H.pylori infection through urease breath test (UBT) with 14 carbon. Finally, two groups are going to compare about succeeding in eradication of H.pylori infection.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201310221155N17**
Registration date: **2014-09-03, 1393/06/12**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-09-03, 1393/06/12

Registrant information

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Farahnaz Joukar
Name of organization / entity
Guilan University of Medical Sciences, Gastrointestinal and liver disease Research Center
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Guilan University of Medical Sciences

Expected recruitment start date

2013-10-23, 1392/08/01

Expected recruitment end date

2014-08-23, 1393/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparision of two quadriple regimen amoxicillin, bismuth subsalicylate, pantoprazole, clarythromycin and amoxicillin, bismuth subsalicylate, pantoprazole, gemifloxacin in eradication of H.pylori infection

Public title
The effect of gemifloxacin in treatment of H.pylori infection
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: New cases of H.pylori infection; patients between 18 to 80 years old Exclusion criteria: The pregnant and brest feeding women; gastric and esophagial malignancies; pylor stenosis; iiver cirrhosis; opium addicts; hypersensitivity to amoxicillin; bismuth subsalicylate; pantoprazole; clarythromycin; gemifloxacin; using cholestyramine; renal failure; history of sizzure; favism and hematologic disorders; incomplete treatment (under 80%); consent to continue treatment; history of H.pylori treatment
Age
From **18 years** old to **80 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **182**
Randomization (investigator's opinion)
Randomized
Randomization description
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
Guilan University of Medical Sciences. Ethics Committee of Gastrointestinal and Liver Diseases Resea
Street address
Sardar Jangal Ave, Gastrointestinal and Liver Diseases Research Center, Razi Hospital, Rasht, Iran
City
Rasht
Postal code
955655-41488
Approval date
2010-09-23, 1389/07/01
Ethics committee reference number
175-ش

Health conditions studied

1

Description of health condition studied
Dyspepsia
ICD-10 code
k30
ICD-10 code description
Dyspepsia

Primary outcomes

1

Description
Helicobacter pylori eradication
Timepoint
12 weeks
Method of measurement
Ureas Breath Test with C14

Secondary outcomes

1

Description
Comparision of two quadriple regimen amoxicillin, bismuth subsalicylate, pantoprazole, clarythromycin and amoxicillin, bismuth subsalicylate, pantoprazole, gemifloxacin in eradication of H.pylori infection
Timepoint
8-12 weeks
Method of measurement
UBT

Intervention groups

1

Description
Control group take cap amoxicillin 500 miligram two numbers every 12 hours, tab bismuth subsalicylate 120 miligram two numbers every 12 hours, tab pantoprazole 20 miligram one number daily, tab clarythromycin 500 miligram one number every 12 hours for 10 days period
Category
Treatment - Drugs

2

Description
Intervention group take cap amoxicillin 500 miligram two numbers every 12 hours, tab bismuth subsalicylate 120 miligram two numbers every 12 hours, tab pantoprazole

20 miligram one number daily, tab gemifloxacin 320 miligram one number daily for 10 days period

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Gastrointestinal and Liver Diseases Research Center

Full name of responsible person

Dr. Fariborz Mansour ghanei

Street address

Sardar Jangal Ave, Gastrointestinal and Liver Diseases Research Center, Razi Hospital, Rasht, Iran

City

Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Guilan Univercity of Medical Sciences

Full name of responsible person

Dr Rasool Tabari KHomeirani

Street address

Sadati st, Samjoo st, Rasht,Guilan

City

Rasht

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Guilan Univercity of Medical Sciences

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

Contact

Name of organization / entity

Gastrointestinal and Liver Diseases Research Center

Full name of responsible person

Farahnaz Joukar

Position

Gastrointestinal and Liver Diseases Research Center

Other areas of specialty/work

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Position

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Other areas of specialty/work

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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