Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of helicobacter pylori eradication of fourteen days regimen of four medications “bismuthe subcirate, pantoprazole, amoxicilline, clarithromycin” with seven days sequential regimen of “bismuthe subcirate, pantoprazole, amoxicilline, meteronidazole” and “bismuthe subcirate, pantoprazole, amoxicilline, furazolidone”

Protocol summary

Summary

We decided to compare a routine regimen with a sequential one. This study is the third phase of a double blind clinical trial, which would be done in a 6 months period during the year of 1396. 344 persons were chosen random block in a specific time period from the people referred to the endoscopy department, which had a positive helicobacter pylori endoscopic report. They were divided into two 172 groups, one group treated with the 14 days regimen of “bismuthe subcirate 240 mg twice a day made by Kimidarou, pantoprazole 20 mg twice a day made by Takeda, amoxicilline 1 gr twice a day made by Kosar, clarithromycin 500 mg twice a day made by Actover , and the sequential regimen; first 7 days of bismuthe subcirate 240 mg twice a day made by Kimidarou, pantoprazole 20 mg twice a day made by Takeda, amoxicilline 1 gr twice a day made by Kosar, meteronidazole 500 mg twice a day made by abidi, and second 7 days with bismuthe subcirate 240 mg twice a day made by Kimidarou, pantoprazole 20 mg twice a day made by Takeda, amoxicilline 1 gr twice a day made by Kosar, and furazolidone 100 mg twice a day made by Tehran Darou). An UBT with carbon 14 would be done 4 weeks after the end of the treatment to find out the efficacy of the therapeutic regimens. In addition, we would evaluate the side effects 2 weeks after the initiation of the treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201708071155N26**

Registration date: **2017-08-08, 1396/05/17**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-08-08, 1396/05/17

Registrant information

Name

Farahnaz Joukar

Name of organization / entity

Guilan University of Medical Sciences, Gastrointestinal and liver disease Research Center

Country

Iran (Islamic Republic of)

Phone

+98 13 1553 5116

Email address

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Recruitment status

Recruitment complete

Funding source

Guilan Univercity of Medical Sciences

Expected recruitment start date

2017-07-13, 1396/04/22

Expected recruitment end date

2018-01-12, 1396/10/22

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of helicobacter pylori eradication of fourteen days regimen of four medications “bismuthe subcirate, pantoprazole, amoxicilline, clarithromycin” with seven days sequential regimen of “bismuthe subcirate, pantoprazole, amoxicilline, meteronidazole” and “bismuthe subcirate, pantoprazole, amoxicilline, furazolidone”

Public title
The effect of fourteen days regimen of four medications “bismuthe subcirate, pantoprazole, amoxicilline, clarithromycin” and seven days sequential regimen of “bismuthe subcirate, pantoprazole, amoxicilline, meteronidazole” and “bismuthe subcirate, pantoprazole, amoxicilline, furazolidone” in helicobacter pylori eradication
Purpose
Treatment
Inclusion/Exclusion criteria
• Inclusion criteria: Positive helicobacter pylori in the endoscopy and no therapeutic regimen for treatment • Exclusion criteria: Pregnant and breast feeding women, gastric and esophageal malignancy, cirrhosis, heart and kidney failure, history of seizure, hematologic diseases, and allergy to medications, patients with incomplete treatment period, severe side effects, and no satisfaction to continue treatment
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **344**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
No Comment

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Guilan University of Medical Sciences.
Street address
Gaz square ,Shaheed Beheshti street,Research and Technology Deputy Rasht, Iran
City
Rasht
Postal code
4193893345
Approval date
2017-07-12, 1396/04/21
Ethics committee reference number
IR.GUMS.REC.1396.141

Health conditions studied

1

Description of health condition studied
Helicobacter pylori
ICD-10 code
B98.0
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
12 weeks
Method of measurement
Ureas Breath Test with C14

Secondary outcomes

1

Description
Comparison of helicobacter pylori eradication of fourteen days regimen of four medications “bismuthe subcirate, pantoprazole, amoxicilline, clarithromycin” with seven days sequential regimen of “bismuthe subcirate, pantoprazole, amoxicilline, meteronidazole” and “bismuthe subcirate, pantoprazole, amoxicilline, furazolidone”
Timepoint
2-4 weeks
Method of measurement
2-4 weeks

Intervention groups

1

Description
Intervention group takethe 14 days treatment of bismuthe subcirate 240 mg twice a day made by Kimidarou, pantoprazole 20 mg twice a day made by

Takeda, amoxicilline 1 gr twice a day made by Kosar, clarithromycin 500 mg twice a day made by Actover , and the sequential regimen; first 7 days of bismuthe subcirate 240 mg twice a day made by Kimidarou, pantoprazole 20 mg twice a day made by Takeda, amoxicilline 1 gr twice a day made by Kosar, meteronidazole 500 mg twice a day made by abidi, and second 7 days with bismuthe subcirate 240 mg twice a day made by Kimidarou, pantoprazole 20 mg twice a day made by Takeda, amoxicilline 1 gr twice a day made by Kosar, and furazolidone 100 mg twice a day made by Tehran Darou.

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 ghanaei

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.Mir saeed attarchi

Street address

Sadati st, Samjoo st, Rasht,Guilan

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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

Dr. Farahnaz Joukar

Position

Deputy of Gastrointestinal and Liver Diseases Research Center

Other areas of specialty/work

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Contact

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Position

Full Professor of Internal Medicine & Gastroenterology

Other areas of specialty/work

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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