

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 2026

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

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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 subcitate, pantoprazole, amoxicilline, clarithromycin” with seven days sequential regimen of “bismuthe subcitate, pantoprazole, amoxicilline, meteronidazole” and “bismuthe subcitate, pantoprazole, amoxicilline, furazolidone”

Public title

The effect of fourteen days regimen of four medications “bismuthe subcitate, pantoprazole, amoxicilline, clarithromycin” and seven days sequential regimen of “bismuthe subcitate, pantoprazole, amoxicilline, meteronidazole” and “bismuthe subcitate, 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 subcitate, pantoprazole, amoxicilline, clarithromycin” with seven days sequential regimen of “bismuthe subcitate, pantoprazole, amoxicilline, meteronidazole” and “bismuthe subcitate, pantoprazole, amoxicilline, furazolidone”

Timepoint

2-4 weeks

Method of measurement

2-4 weeks

Intervention groups

1

Description

Intervention group take the 14 days treatment of bismuthe subcitate 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 subcitate 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 subcitate 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 University of Medical Sciences

Full name of responsible person

Dr.Mir saeed attarchi

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 University 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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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