Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jun 2026

Comparision of H.pylori eradication rate in quadriple regimen " Bismuth subcytrate , Pantazol,Amoxicillin, Formilid and Probiotic(Lactobacillus reuteri)” with quadriple regimen " Bismuth subcytrate, Pantazol,Amoxicillin, Formilid and placebo.

Protocol summary

Study aim
Comparision of H.pylori eradication rate in quadriple regimen"Bismuth subcytrate,Pantazol,Amoxicillin, Formilid and Lactobacillus reuteri” with placebo.

Design
The present study is a phase 3 randomized clinical trial.The subjects were divided into two groups of 210 people as Block randomization.420 subjects were studied using available sampling and in the form of Double Blind, which neither the patient nor the physician will know about the drug.

Settings and conduct
The study was performed as multi-center study at Caspian Digestive Disease Research Center, Gastrointestinal and liver Disease Research Center and GI Cancer Screening and Prevention Disease

Participants/Inclusion and exclusion criteria
Inclusion criteria: Positive H. Pylori in the endoscopy; Not receiving therapeutic regimen for treatment; People over the age of 18 years. Non-inclusion criteria: Pregnant and breast feeding women; Gastric and esophageal malignancy; Cirrhosis; Heart and kidney failure; Diabetes,...

Intervention groups
Intervention group1: Treated with 14-day quadruple regimen including Bismuth subcytrate 240 mg 2 times daily, Pantazol 40 mg twice daily, Amoxicillin1 g 2 times daily, Formilid 500 mg and Lactobacillus reuteri 100 mg 2 times daily. The first two weeks they will be treated with probiotic with quadruple regimen and two weeks later only antibiotics . Intervention group 2: Treated with 14-day quadruple regimen mentioned above with Placebo twice daily and only placebo will be given weekly that antibiotics will be given two weeks later. The first two weeks they will be treated with placebo with quadruple regimen and two weeks later only antibiotics.

Main outcome variables
H.pylori eradication

General information

Reason for update
Correction of inclusion criteria and correction of pharmaceutical company name

Acronym

IRCT registration information
IRCT registration number: **IRCT20080901001155N32**
Registration date: **2020-05-31, 1399/03/11**
Registration timing: **registered_while_recruiting**

Last update: **2021-05-02, 1400/02/12**
Update count: **1**

Registration date
2020-05-31, 1399/03/11

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

Expected recruitment start date

2019-12-22, 1398/10/01

Expected recruitment end date

2020-08-22, 1399/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparision of H.pylori eradication rate in quadriple regimen " Bismuth subcytrate , Pantazol,Amoxicillin, Formilid and Probiotic(Lactobacillus reuteri)" with quadriple regimen " Bismuth subcytrate, Pantazol,Amoxicillin, Formilid and placebo.

Public title

The effect of quadriple regimen on the eradication rate of Helicobacter pylori

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Positive Helicobacter pylori in the endoscopy No therapeutic regimen for treatment People over the age of 18 years

Exclusion criteria:

Pregnant and breast feeding women Gastric and esophageal malignancy Cirrhosis and Diabetes heart and kidney failure History of seizure, hematologic diseases Immune system deficiency Drug sensitivity including Pentoprazole and Lactobacillus routeri Patients with incomplete treatment With acute gastrointestinal disease (such as acute diarrhea) Chronic gastrointestinal disease (such as inflammatory bowel disease and celiac disease) Kidney failure Nervous disease and those who received antibiotics or acidblocking drugs 6 weeks ago Use of nonsteroidal antiinflammatory drugs (NSAIDs) such as aspirin 3 weeks before treatment or in the past month for any reason

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **420**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants and Health care personnel will not be informed about the type of group therapy they have received.To do this,the placebo drug will be ordered exactly the same as the probiotic and will be available to these people

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Guilan University of Medical Sciences.

Street address

Research and Technology Deputy ,Shaheed Beheshti street,Gaz square

City

Rasht

Province

Guilan

Postal code

41448956655

Approval date

2019-12-21, 1398/09/30

Ethics committee reference number

IR.GUMS.REC.1398.437

Health conditions studied

1

Description of health condition studied

En 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

8 weeks after the end of the treatment

Method of measurement

En Ureas Breath Test with C14

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: 14-day quadruple regimen including "Bismuth subcitrate manufactured by Kamidaroo 240 mg 2 times daily, pantazol 40 mg twice daily by Nycomed, amoxicillin made by Kosar 1 g twice daily, Formilid 500 mg manufactured) Actover" and Probiotic Lacto Bacillus router 100 mg twice a day produced by bio-fermentation company
Category
Treatment - Drugs

2

Description
Intervention group 2: 14-day quadruple regimen including "Bismuth subcitrate manufactured by Kamidaroo 240 mg 2 times daily, Pantazol produced by Nycomed 40 mg twice daily, amoxicillin produced by Kosar company 1 gr twice daily, Formilid 500 mg manufactured by Actover" and Placebo
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Caspian Digestive Disease Research Center
Full name of responsible person
Dr.Fariborz Mansour-Ghanei
Street address
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Sponsors / Funding sources

1

Sponsor
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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
Rasht 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
Name of organization / entity
Rasht University of Medical Sciences
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Dr.Fariborz Mansour-Ghanei
Position
Full Professor of Internal Medicine & Gastroenterology
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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
The main outcome of this study, which is eradication of Helicobacter pylori, will be made available to the general public
When the data will become available and for how long
One year after printing results
To whom data/document is available
Researchers at relevant research centers, universities,

and related doctors

Under which criteria data/document could be used

In this case, the decision has not yet been taken

From where data/document is obtainable

Mehrnaz Asgharnezhad Gastrointestinal and Liver Diseases Research Center, Razi hospital, Rasht
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What processes are involved for a request to access data/document

At the outset, the applicant will email and complete his or her full introduction of the organization and the purpose of obtaining this data and will request the relevant documents or files.Subsequently, the data files will be made available to the applicant within the time period stated by the relevant investigator

Comments