

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 2026

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

Protocol summary

Study aim

Comparison of H.pylori eradication rate in quadruple 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, Amoxicillin 1 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)

Phone

+98 13 1553 5116

Email address

info@gldrc.org

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 quadruple regimen " Bismuth subcytrate , Pantazol,Amoxicillin, Formilid and Probiotic(Lactobacillus reuteri)" with quadruple regimen " Bismuth subcytrate, Pantazol,Amoxicillin, Formilid and placebo.

Public title
The effect of quadruple 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 failire 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

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

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Recruitment center

Name of recruitment center

Gastrointestinal and Liver Disease Research Center

Full name of responsible person

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Recruitment center

Name of recruitment center

GI Cancer Screening and Prevention Research Center

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Dr.Mir Saeed Attarchi

Street address

Sadati st, Samjoo st, Rasht,Guilan

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msattarchi@yahoo.com

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

Full name of responsible person

Dr.Fariborz Mansour-Ghanei

Position

Full Professor of Internal Medicine & Gastroenterology

Latest degree

Subspecialist

Other areas of specialty/work

Specialist in gastrointestinal and liver diseases

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Rasht University of Medical Sciences

Full name of responsible person

Dr. Farahnaz Joukar

Position

Deputy of Gastrointestinal and Liver Diseases
Research Center

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

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Person responsible for updating data**Contact****Name of organization / entity**

Rasht University of Medical Sciences

Full name of responsible person

Mehrnaz Asgharnezhad

Position

Master of Nursing

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

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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
00981333535116, 955655-41448
asgharnezhad98@yahoo.com

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