

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 2026

Comparing the five-drug regimen (Bismuth sub-citrate , Omeprazole , Amoxicillin , Clarithromycin , Tinidazole) and (Bismuth sub citrate , Omeprazole , Tetracycline , Metronidazole , Ofloxacin) on the eradication rate of Helicobacter pylori infection in non responder dyspeptic patients

Protocol summary

Summary

This study compared two five-drug regimen , Protocol I (Bismuth sub citrate , Omeprazole , Amoxicillin , Clarithromycin , Tinidazole) and Protocol II (Bismuth sub citrate , Omeprazole , Tetracycline , Metronidazole and Ofloxacin) on the eradication rate of Helicobacter pylori infection in dyspeptic patients resistant to treatment. The sample census will be the method in this way all patients referred to digestive clinics in Rasht that under drug treatment and resistant to quadruple or triple regimen and did not show a positive response during a year are enrolled. Helicobacter pylori positive patients over 15 years and less than 65 years that under regimen triple or quadruple drugs and urea breath test (UBT) using carbon 14 (C14 or C13 or stoolAg) with the European protocol were positive again , enter are studied. The patients are divided into two categories : The first group under five drug regimen (Bismuth sub citrate 240 milligram two time in day , Omeprazole 20 milligram two time in day, Amoxicillin 1 gram two time in day, Clarithromycin 500 milligram two time in day , Tinidazole 500 milligram two time in day and the second group treated with Bismuth sub-citrate 240 milligram two time in day , Omeprazole 20 milligram two time in day , Tetracycline 500 milligram two time in day , Metronidazole 500 milligram two time in day , Ofloxacin 200 milligram two time in day) for a week. Then , after the end of 12 weeks of treatment to evaluate treatment with C13 UBT and stool antigen (stool Ag) Eradication will be used and if the negative will be considered. If any of the positive tests of helicobacter pylori positive patients considered to be. Also on the end of a week after treatment of drug side effects and the amount of drug use by patients examined.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201103011155N11**

Registration date: **2011-07-03, 1390/04/12**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-07-03, 1390/04/12

Registrant information

Name

Farahnaz Joukar

Name of organization / entity

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

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Recruitment status

Recruitment complete

Funding source

vice chancellor for research Guilan university of medical sciences

Expected recruitment start date

2011-02-09, 1389/11/20

Expected recruitment end date

2012-02-09, 1390/11/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the five-drug regimen (Bismuth sub-citrate , Omeprazole , Amoxicillin , Clarithromycin , Tinidazole) and (Bismuth sub citrate , Omeprazole , Tetracycline , Metronidazole , Ofloxacin) on the eradication rate of Helicobacter pylori infection in non responder dyspeptic patients

Public title

Comparing regimens (Bismuth sub-citrate , Omeprazole , Amoxicillin , Clarithromycin , Tinidazole) and (Bismuth sub citrate , Omeprazole , Tetracycline , Metronidazole , Ofloxacin) on the eradication rate of Helicobacter pylori infection in non responder dyspeptic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion: In this study , helicobacter pylori positive patients over 15 years and less than 65 years that under drug treatment regiment quadruple or triple placed urea breath test (UBT) using carbon 14 (C14 or C13 or stoolAg) with the European protocol again have been positive , will enter the study. Exclusion : Pregnant women , Patients with gastric malignancy , Cirrhosis , Patients with allergy to Amoxicillin or Clarithromycin , Omeprazole , Tetracycline , Ofloxacin , Metronidazole and Tinidazole , Colestramin Consumption , Renal failure , History of seizures , Blood disorders , Fauvism and treatment of patients with incomplete (less than 80%) will be excluded.

AgeFrom **15 years** old to **65 years** old**Gender**

Both

Phase

2

Groups that have been masked*No information***Sample size**

Target sample size:

Randomization (investigator's opinion)

N/A

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 Gastrointestinal and Liver Diseases Research

Street address

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

City

Rasht

Postal code

955655-41488

Approval date

2011-03-03, 1389/12/12

Ethics committee reference number

160/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 week

Method of measurement

ureas breath test with c14 and stool antigen

Secondary outcomes

empty

Intervention groups**1****Description**

The first group treated with diet five drug protocol I (Bismuth sub citrate 240 miligram two time in day Construction Company Kimdaru drug 120 miligram of two every 12 hours is given , Omeprazole 20 miligram two time in day Construction Company doctor abidi capsule 20 miligram every 12 hours of a number , Amoxicillin 1 gram two time in day Construction Co , two 500 mg capsules every 12 hours , Clarithromycin 500 miligram two time in day Abbott Construction Company a number every 12 hours , making pars

Tinidazole 500 miligram two time in day drug every 12 hours that a number of drug to be prescribed for a week.

Category
Treatment - Drugs

2

Description

Another group treated with protocol II (Bismuth sub citrate 240 miligram two time in day Construction Co Kimydaru one number per 12 hours , Omeprazole 20 miligram two time in day Construction Company doctor abidi a number every 12 hours , Tetracycline 500 miligram two time in day Construction Company Razak two every 12 hours , Metronidazole 500 miligram two time in day Construction Company Alborz number every 12 hours , Ofloxacin 200 miligram two time in day Construction Co. exir number every 12 hours a week will be given.

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
Vince chancellor for reaserch guilan univercity of medical sciences

Full name of responsible person
Sadati st, Samjoo st, Rasht,Guilan

Street address
Dr Rasool Tabari KHomeirani

City
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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
Vince chancellor for reaserch 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

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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