Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The comparison between effects and side effects of seven days or ten days quadruple therapy regimens (Bismuth sub citrate, Levofloxacin, Amoxicillin and Pantazole) in eradication of H.pylori infection.

Protocol summary

Summary

This study is a clinical trial which aims to compare the efficacy and adverse effects of seven and ten-day quadruple regimen in the treatment of patients with H. pylori referred to the gastroenterology and liver Clinic in Rasht. H. Pylori infection is confirmed according to carbon-13 or 14-UBT, pathology or stool antigen. Demographic data, smoking and commodities recorded for all patients. Then patients are randomly divided into two groups. The first group is treated with four drugs (bismuth sub citrate, levofloxacin, amoxicillin, pantozol) for seven days. The second group received the same formula for a period of ten days. Complications are recorded for both groups 2 weeks after treatment. Eight weeks after the treatment, Urea Breath Test (with carbon 14) is done for patients to determine resistance or eradication of infection.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201406141155N19**
Registration date: **2015-07-10, 1394/04/19**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2015-07-10, 1394/04/19

Registrant information

Name

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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

Gastrointestinal and Liver Diseases Research Center, Guilan University of Medical Sciences

Expected recruitment start date

2015-07-15, 1394/04/24

Expected recruitment end date

2015-11-22, 1394/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison between effects and side effects of seven days or ten days quadruple therapy regimens (Bismuth sub citrate, Levofloxacin, Amoxicillin and Pantazole) in eradication of H.pylori infection.

Public title

Compare seven and ten days quadruple regimen for H. pylori

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: H. pylori infection has been confirmed in accordance with Urea Breath Test with carbon-13 or 14 or pathology or stool antigen, The patient satisfaction
Exclusion criteria: Pregnant and lactating women,

Patients with esophageal cancer, Liver cirrhosis, Heart failure; kidney failure, History of seizures, Hematologic diseases; Allergy to drugs, Patients with an incomplete course of treatment; Severe complications; Discontent to treatment

Age
From **18 years** old to **80 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **220**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee Guilan University of Medical Sciences .

Street address
Namjoo Ave

City
Rasht

Postal code

Approval date
2014-07-14, 1393/04/23

Ethics committee reference number
1930175713

Health conditions studied

1

Description of health condition studied
Helicobacter pylori infection

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
Eradication of infection

Timepoint
Eight weeks after completion of treatment

Method of measurement
Urea breath test (Carbon 14)

Secondary outcomes

1

Description
Complications

Timepoint
Two weeks after completion of treatment

Method of measurement
According to the case history

Intervention groups

1

Description
Administration of quadruple therapy for seven days as follows: Bismuth sub citrate (Chemidarou company) 240 mg BID, Levofloxacin (Abidi company) 500 mg daily, Amoxicillin (Chemidarou company) 1 g BID, Pantozol (Nokomed company) 20 mg BID

Category
Treatment - Drugs

2

Description
Administration of quadruple therapy for ten days as follows: Bismuth sub citrate (Chemidarou company) 240 mg BID, Levofloxacin (Abidi company) 500 mg daily, Amoxicillin (Chemidarou company) 1 g BID, Pantozol (Nokomed company) 20 mg BID

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Gastrointestinal and Liver Diseases Research Center, Guilan

Full name of responsible person
Dr. Mansour Ghanaei Fariborz

Street address
Gastrointestinal and Liver Diseases Research Center, Razi hospital, Sardar jangle Ave

City
Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vince Chancellor for Research Guilan University of Medical Sciences .

Full name of responsible person
Dr. Tabari Khomeirani Rasool

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Sadati St, Namjoo Ave

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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 Research 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
Guilan Gastrointestinal and Liver Diseases Research Center

Full name of responsible person
Joukar Farahnaz

Position
Assistant in Guilan Gastrointestinal and Liver Diseases Research Center

Other areas of specialty/work

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Person responsible for updating data

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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