Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparing clarithromycin-based triple therapy Helicobacter pylori eradication with triple therapy containing levofloxacin

Protocol summary

Summary

aims: Comparing clarithromycin-based triple therapy Helicobacter pylori eradication with triple therapy containing levofloxacin Inclusion criteria:All patients underwent endoscopy with duodenal ulcer or gastric or duodenal or stomach inflammation and Erosoin Sari hospital clinic professor Gu reported that Helicobacter pylori positive and study are older than 18 years Exit key criteria: During the last two weeks, patients with PPI or H2 RA (histamine 2 receptor antagonist), or within the last 4 weeks have received antibiotics or bismuth; Concomitant use of anticoagulants ;corticosteroids or ketoconazole; Patients with a history of stomach surgery; Patients with peptic ulcer bleeding complication refer and endoscopy used to control bleeding Sample: 120 Intervention and time: Patients with duodenal ulcer or gastric or duodenal or stomach inflammation and erosion after endoscopic diagnosis of Helicobacter pylori positive test randomly placed in two groups A and B ,Patients with duodenal ulcer or gastric or duodenal or stomach inflammation and erosion after endoscopic diagnosis of Helicobacter pylori positive test randomly placed in two groups A and B Patients through random table into randomly receive one of the two regimes. A:pantoprazole 40mg/bd-Amoxicilin1g/-Clarithromycin500/bd B:pantoprazole 40mg/bd-Amoxicilin1g/-levofloxacine500/dailyto 10days

General information

Acronym

CCTTHPCWLCTT

IRCT registration information

IRCT registration number: **IRCT2015110224825N1**
Registration date: **2016-02-09, 1394/11/20**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-02-09, 1394/11/20

Registrant information

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Recruitment status

Recruitment complete

Funding source

Mazandaran University Of Medical Sciences

Expected recruitment start date

2015-03-20, 1393/12/29

Expected recruitment end date

2015-11-21, 1394/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing clarithromycin-based triple therapy Helicobacter pylori eradication with triple therapy containing levofloxacin

Public title

Clarithromycin containing triple therapy Helicobacter pylori eradication compared with levofloxacin containing triple therapy

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: All patients underwent endoscopy with duodenal ulcer or gastric or duodenal or stomach inflammation and Erosion referred to the clinic / office professor interviewed Sari hospital reported that Helicobacter pylori positive and study are older than 18 years Exclusion criteria: Pregnancy and breastfeeding; H. pylori eradication has already been received; During the last two weeks patients with PPI or H2 RA (histamine 2 receptor antagonist), or within the last 4 weeks have received antibiotics or bismuth; Concomitant use of anticoagulants; corticosteroids or ketoconazole; Patients with a history of stomach surgery; Patients with advanced disease confirmed and severe cardiac; pulmonary;Endocrine; chronic renal failure; chronic liver disease and cancer; alcohol consumption; With a history of peptic ulcer bleeding ulcer complications

Age

From **76 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

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

Mazandaran University Of Medical Sciences-Department of Research and Technology

Street address

Mazandaran,Sar,Moalem Street,Department of Research and Technology

City

Sari

Postal code

4817844718

Approval date

2015-12-19, 1394/09/28

Ethics committee reference number

IR.MAZUMS.REC.94-1880

Health conditions studied

1

Description of health condition studied

Eradication of 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

Eradication of Helicobacter pylor

Timepoint

10 days after treatment,4 Weeks after treatment ppI,Four weeks after discontinuation of medication for respiratory test

Method of measurement

Through the breath test 14 C- UBT

Secondary outcomes

1

Description

Headache،Dizziness،Confusion

Timepoint

During the course of treatment

Method of measurement

Calling and patient interview

2

Description

Bitter mouth

Timepoint

During the course of treatment

Method of measurement

Calling and patient interview

3

Description

Diarrhea-vomiting

Timepoint

During the course of treatment

Method of measurement

Calling and patient interview

4

Description

Skin complications

Timepoint

During the course of treatment

Method of measurement
Calling and patient interview

5

Description
Nausea , abdominal pain
Timepoint
During the course of treatment
Method of measurement
Calling and patient interview

6

Description
Side effects reported by patients include hypersensitivity reactions
Timepoint
During the course of treatment
Method of measurement
Calling and patient interview

7

Description
Constipation Decreased appetite
Timepoint
During the course of treatment
Method of measurement
Calling and patient interview

8

Description
Changes in taste
Timepoint
During the course of treatment
Method of measurement
Calling and patient interview

Intervention groups

1

Description
Control group: Panto Prazol 40 mg twice daily , amoxicillin 1g , clarithromycin 500 mg twice daily for 10 days
Category
Treatment - Drugs

2

Description
Groups intervention: pantoprazole 40 mg twice daily, amoxicillin 1 g, levofloxacin 500 mg once daily for 10 days
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Clinic Mr.Dr Fakheri
Full name of responsible person
Mr Fakheri
Street address
Mazandaran,Sari,Street Qarn,Clinic Mr .Dr Fakheri
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of medical sciences,Deputy of Research and Technology
Full name of responsible person
Mr. Dr. Enayati
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Grant name
IR.MAZUMS.REC.94-1880
Grant code / Reference number
۱۸۸۰
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mazandaran University of medical sciences,Deputy of Research and Technology
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
Mazandaran University of Medical Sciences,Deputy of Research and Technology
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Mr. Dr Fakheri
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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