

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 2026

Comparison of Sequential therapy for eradication of H. Pylori infection in renal failure patients

Protocol summary

2012-03-01, 1390/12/11

Summary

Aim: to study the effect of Sequential treatment regimen on H. pylori eradication in chronic renal failure and non-uremic patients. Sample size is 80. Inclusion criteria: patients with dyspepsia symptoms over the past one month from gastroenterology or nephrology clinic or hospital dialysis ward who have infection with H. Pylori confirmed by rapid urease test and biopsy in endoscopy. Exclusion Criteria : taking antibiotic regimen to eradicate H. pylori and or receiving proton pump inhibitors, Bismuth, or NSAID during the last month; concomitant anticoagulant, corticosteroid or Ketoconazole; history of gastric or esophageal surgery; sensitivity to antibiotics; negative endoscopic biopsy; drinking alcohol and smoking; pregnancy and lactation; severe heart disease; diseases of the thyroid gland. The primary outcome: eradication of Helicobacter pylori infection. Interventions: Pantoprazul (BD40mg) and Amoxicillin (if keratinize clearance is between 10-30: 250-500mg BD and if it is less than 10: 250-500 mg Daily) for 5 days and then Pantoprazul (40mg BD) and clarithromycin (250 mg BD) and tinidazole (500mg BD) for 5 days. Control Group: Pantoprazul (40mg BD) and Claritromicine (250 mg BD) and Amoxicillin (if Kratinize cearence is between 10-30: 250-500mg BD and if it is less than 10: 250-500 mg Daily)

Registrant information

Name

Atieh Makhloogh

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Mazandaran University of Medical Sciences

Expected recruitment start date

2010-09-11, 1389/06/20

Expected recruitment end date

2011-07-11, 1390/04/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201201231241N3**

Registration date: **2012-03-01, 1390/12/11**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

Scientific title

Comparison of Sequential therapy for eradication of H. Pylori infection in renal failure patients

Public title

Comparison of Sequential therapy for eradication of H. Pylori infection in renal failure patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with dyspepsia symptoms over the past one month from gastroenterology or nephrology

clinic or hospital dialysis ward who have infection with H. Pylori confirmed by rapid urease test and biopsy in endoscopy. Exclusion Criteria : taking antibiotic regimen to eradicate H. pylori and or receiving proton pump inhibitors, Bismuth, or NSAID during the last month; concomitant anticoagulant, corticosteroid or Ketoconazole; history of gastric or esophageal surgery; sensitivity to antibiotics; negative endoscopic biopsy; drinking alcohol and smoking; pregnancy and lactation; severe heart disease; diseases of the thyroid gland or liver cancer; chronic renal failure patients who are prior to stage 5 or have not received renal replacement therapy.

Age

From **20 years** old to **75 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

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

Mazandaran University of Medical Sciences

Street address

Building No. 2 of University, Moallem Square

City

Sari

Postal code

Approval date

2012-01-08, 1390/10/18

Ethics committee reference number

88-5

Health conditions studied

1

Description of health condition studied

Helicobacter pylori infection

ICD-10 code

B98.0

ICD-10 code description

Helicobacter pylori

Primary outcomes

1

Description

Eradication of Helicobacter pylori Infection

Timepoint

At the end of four weeks after treatment

Method of measurement

Urea Test

2

Description

Eradication of Helicobacter pylori Infection

Timepoint

At the end of four weeks after treatment

Method of measurement

Creatinine Clearance Test

3

Description

Eradication of Helicobacter pylori Infection

Timepoint

At the end of four weeks after treatment

Method of measurement

Stool examination

4

Description

Eradication of Helicobacter pylori Infection

Timepoint

At the end of four weeks after treatment

Method of measurement

Biopsy by Endoscopic

Secondary outcomes

1

Description

Acute Renal Failure

Timepoint

At the first and second weeks of treatment

Method of measurement

Testing Urea

2

Description

Acute Renal Failure

Timepoint

At the first and second weeks of Treatment

Method of measurement

creatinine clearance test

3

Description

Acute Renal Failure

Timepoint

at the first and second weeks of treatment

Method of measurement

weight

Intervention groups

1

Description

Intervention Group:Pantoprazul (BD40mg) and amoxicillin (If keratinize clearance is between 10-30:250-500mg BD and if it is less than 10:250-500 mg Daily)for 5 days and Then Pantoprazul (40mg BD) and clarithromycin (250 mg BD) and tinidazole (500mg BD) for 5 days

Category

Treatment - Drugs

2

Description

Control Group : Pantoprazul (40mg BD) and Claritromicine(250 mg BD)and Amoxicillin (If Kratinize Cearance is between 10-30:250-500mg BD and if it is less than 10:250-500 mg Daily)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital in Sari

Full name of responsible person

Dr Atieh Makhloogh

Street address

Imam Khomeini Hospital,Amir Mazandarani Boulevard

City

Sari

2

Recruitment center

Name of recruitment center

Fatemeh Zahra Hospital of Sari

Full name of responsible person

Dr Atieh Makhloogh

Street address

Fatemeh Zahra Hospital, Artesh Boulevar

City

Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Department of Research and Technology,
Mazandaran University of Medical Sciences

Full name of responsible person

Dr Ahmadali Enayati

Street address

Building No. 2 of University, Moallem Square

City

Sari

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Department of Research and Technology, Mazandaran
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

Mazandaran University of Medical Sciences

Full name of responsible person

Dr Atieh Makhloogh

Position

Associate Professor/Nephrologist

Other areas of specialty/work

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

Mazandaran University of Medical Sciences

Full name of responsible person

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Position

Associate Professor/Nephrologist

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Web page address**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