Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

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

Protocol summary

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. pyloriand 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 cearance is between 10-30: 250-500mg BD and if it is less than 10: 250-500 mg Daily)

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

2012-03-01, 1390/12/11

Registrant information

Name
Atieh Makhlough
Name of organization / entity
Mazandaran University of Medical Sciences
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Iran (Islamic Republic of)
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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

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. pyloriand 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 Makhlough
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 Makhlough
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 Makhlough
Position
Associate Professor/Nephrologist
Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

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Email
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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