Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of Sequential therapy with standard therapy for eradication of H.Pylori infection in uremic patients

Protocol summary

Summary

Our objective is to evaluate effect of sequential therapy in the eradication of H. Pylori infection in uremic patients. 40 patients with age more than 18 years, dyspepsia during last month and positive H.pylori infection (positive rapid urease test and positive biopsy by endoscope) were randomly allocated into two matched (for age and sex) equal groups to treat with either sequential or standard therapy. Standard regimen: Amoxicillin (250-500 mg BD for creatinine clearances 3-10 mg/dl, 250-500 mg Daily for creatinine clearances lower than 10mg/dl), Pantoprazole (40 mg BD) and Claithromycin(250 mg BD). Sequential regimen: Pantoprazole (40mg BD) Amoxicillin (250-500 mg BD for creatinine clearances 3-10mg/dl, 250-500 mg Daily for creatinine clearances lower than 10mg/dl) for the first five days and Clarithromycin (250 mg BD) and Tindazole (500mg BD) and Pantoprazole (40mg BD) for the last five days. Doses were adjusted for creatinine levels. The primary outcome is eradication of H.Pylori measured using stool exam for H.Pylori antigen after 3 months treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138706211241N1**
Registration date: **2009-07-15, 1388/04/24**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2009-07-15, 1388/04/24

Registrant information

Name

Atieh Makhlough

Name of organization / entity

Mazandaran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Mazandaran University of Medical Sciences and Health Sciences

Expected recruitment start date

2009-08-23, 1388/06/01

Expected recruitment end date

2010-08-23, 1389/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Sequential therapy with standard therapy for eradication of H.Pylori infection in uremic patients

Public title

Comparison of Sequential therapy with standard therapy for eradication of H.Pylori infection in uremic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age more than 18 years, dyspepsia during last month and positive H.pylori infection (positive rapid urease test and positive biopsy by endoscope). Exclusion criteria: Antibiotic therapy for eradication of H.pylori, consumption of Proton Pump Inhibitor, H2

blockers, Bismuth, or NSAIDS during last month, consumption of anticoagulants, Ketoconazol or corticosteroids, history of gastric or esophageal surgery, hypersensitivity to antibiotics, negative biopsy of GI, smoking or alcohol use, pregnancy, lactation, severe heart diseases (MI, EF ≤ 30), liver & thyroid diseases and malignancy.

Age
From **20 years** old to **70 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **40**

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 and Health Services

Street address
Mazandaran University of Medical Sciences, Imam Sq, Joybar 3 way,

City
Sari

Postal code

Approval date
empty

Ethics committee reference number
88-4

Health conditions studied

1

Description of health condition studied
H. Pylori infection

ICD-10 code
B96.8

ICD-10 code description
Other specified bacterial agents as the cause of diseases classified to other chapters

Primary outcomes

1

Description
Eradication of H. Pylori infection

Timepoint
3 month after treatment

Method of measurement
Stool antigen test

Secondary outcomes

empty

Intervention groups

1

Description
Intrvention group: seqential treatment:Pantoprazole (40mg BD) Amoxicillin (if clearances of cratinin is between 3-10 mg/dl 250-500 mg BD and if it is lower 10mg/dl 250-500 mg Daily, (for the first five days and Claithromycin (250 mg BD) and Tindazole (500mg BD) and Pantoprazole (40mg BD) for the last five days

Category
Treatment - Drugs

2

Description
Control group: Standard regimen: Amoxicillin (if clearances of cratinine is between 3-10 mg/dl 250-500 mg BD and if it is lower 10mg/dl 250-500 mg Daily), Pantoprazole (40 mg BD) and Claithromycin (250 mg BD)

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Tuba clinic

Full name of responsible person
Atieh Makhlough

Street address
Tuba clinic, Khazar boulevared

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences and Health Services

Full name of responsible person
Sayed Jalal Hosseini Mehr

Street address
Moalem sq.

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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
Mazandaran University of Medical Sciences and Health Services

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 Univercity of Medical Sciences and Health Services

Full name of responsible person
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Position
Associated professor/Aademic staff of mazandaranl univercity of medical sciences

Other areas of specialty/work

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Person responsible for scientific inquiries

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Position
Nephrologist/Associate Professor/Aademic staff ofmazandaranl univercity of medical sciences

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Position
Nephrologist/Associated professor Academic Member of Mazandaran Univercity

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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