

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 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 Makhloogh

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 \leq 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: sequential 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 Makhloogh

Street address

Tuba clinic, Khazar boulevard

City

Sari

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.

City

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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 University of Medical Sciences and Health Services

Full name of responsible person

Atieh Makhloogh

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

Contact

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Full name of responsible person

Atieh Makhloogh

Position

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

Other areas of specialty/work

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Full name of responsible person

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Position

Nephrologist/Associated professor Academic Member of Mazandaran University

Other areas of specialty/work

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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