

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

comparison of 14 days hybrid therapy with 14 days standard triple therapy on eradication of H.pylori in hemodialysis patients

Protocol summary

Summary

The main objective of this Study was to Eradicate Helicobacter pylori infection in Patients undergoing Hemodialysis. Patients on inclusion criteria patients on hemodialysis for at least 3 months who have GI symptoms such as Dyspepsia or Epigastric pain or referred for Evaluation of H.pylori infection before Renal Transplantation or for Evaluation of Iron Deficiency Anemia , Endoscopy has done and H.pylori confirmed by at least one positive test out of the following : Rapid Urease test or Histology or stool Antigen Test and Exclusion criteria Similar age less than 18 yr and more than 80 yr .; Advanced Chronic Disease or any other Pathology that Prevents attending controls and follow up; Allergy to any of the Antibiotics in the Treatment ; previous Gastric Surgery ;Pregnancy and Lactation; Previous Eradication Treatment; Consumption of Antibiotics or Bismuth Salts during the last 4 weeks. The Sample size is 60 Hemodialysis patients. They are numbered in a Computerized systematic & incidental Method. Therefore are Categorized into two Groups which are equalized According to Gender and Age. They scheduled to undergo 14 days Triple Therapy or 14 days Hybrid Therapy in a Double Blind Fashion .Triple Therapy include Pantoprazole 40 mg BID and Amoxicilline 500 mg BID and Clarithromycine 500 mg BID for 14 days .Hybrid regimen include pantoprazole 40 mg BID and Amoxicilline 500 mg BID for 14 days plus Clarithromycine 500 mg BID and Tinidazole 500 mg BID for Second 7 days.8 Weeks After End of Treatment Course the Success of Eradication is investigated by Stool Antigen Test .the Positive HPSA Test is defined as Resistance or Unsuccessful Treatment. The Primary Outcome of this Study is to Treat H. pylori Infection in Hemodialysis Patients.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201307221241N4**

Registration date: **2014-11-13, 1393/08/22**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-11-13, 1393/08/22

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 Science . Cellular and Molecular Biological Research Center .

Expected recruitment start date

2013-09-23, 1392/07/01

Expected recruitment end date

2014-09-23, 1393/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison of 14 days hybrid therapy with 14 days

standard triple therapy on eradication of H.pylori in hemodialysis patients

Public title

Helicobacter pylori eradication in end stage renal disease

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: 18 - 80 years patients on hemodialysis for at least 3 months who have GI symptoms such as dyspepsia or epigastric pain , or referred for evaluation of H.pylori infection before renal transplantation , or for evaluation of Iron Deficiency Anemia , endoscopy has done and H.pylori confirmed by at least one positive test out of the following : rapid urease test (RUT) ,or histology , or stool antigen test . Exclusion criteria : -age less than 18 yr and more than 80 yr . -advanced chronic disease or any other pathology that prevents attending controls and follow up . -allergy to any of the antibiotics in the treatment . -previous gastric surgery -pregnancy and lactation -previous eradication treatment consumption of antibiotics or bismuth salts during the last 4 weeks . - concurrent use of anticoagulant or ketoconazole and or steroids -severe heart failure include myocardial infarction or EF < 30 that confirmed by echocardiogram - incooperative patient

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double 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 Science and Health Services

Street address

Moalem Sq

City

Sari

Postal code**Approval date**

2013-09-11, 1392/06/20

Ethics committee reference number

92151

Health conditions studied**1****Description of health condition studied**

Helicobacter 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**

helicobacter pylori infection

Timepoint

begining of study

Method of measurement

rapid urease test and biopsy and stool h.pylori antigen test in begining of study

Secondary outcomes**1****Description**

h.pylori eradication

Timepoint

8 weeks after treatment

Method of measurement

stool h.pylori antigen test

Intervention groups**1****Description**

standard triple therapy include : pantoprazole 40 mg BID + Amoxicilline 500 mg BID + Clarithromycine 500 mg BID for 14 days

Category

Treatment - Drugs

2**Description**

hybrid regimen include :pantoprazole 40 mg BID + Amoxicilline 500 mg BID for 14 days + tinidazole 500 mg BID + Clarithromycine 500 mg BID for second 7 days.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam Khomeini Hospital

Full name of responsible person

Dr Makhluh

Street address

Razi Aveneue

City

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2**Recruitment center****Name of recruitment center**

Fateme zahra hospital

Full name of responsible person

Dr Atieh Makhluh

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3**Recruitment center****Name of recruitment center**

Tuba Clinic

Full name of responsible person**Street address****City**

Sari

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Mazandaran University of Medical Science and Health Services

Full name of responsible person

Dr Atie Makhluh

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Imam sq ; Joybar 3 way

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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 Science 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 Science and Health Services

Full name of responsible person

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Position

Associated professor/Aademic staff of mazandaranl univercity of medical sciences

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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