Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

comparison of 14 days hybrid therapy with 14 days standard triple therapy on erradication 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 Epigasteric 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 fallow 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 Cathegorized into two Groups which are equalized Acourding 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 Makhlough
Name of organization / entity
Mazandaran University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 15 1226 4047
Email address
dr.makhloogh@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mazandaran University of Medical Science . Cellular and Molecular Biolological 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 erradication of H.pylori in hemodialysis patients

Public title
Helicobacter pylori erradication 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 epigasteric pain , or referred for evaluation of H.pylori infection before renal transplantation , or for evaluation of Iron Defficiency 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 fallow 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 pationt
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 Makhlugh
Street address
Razi Aveneu
City
Sari

2

Recruitment center
Name of recruitment center
Fateme zahra hospital
Full name of responsible person
Dr Atieh Makhlough
Street address
Fateme zahra hospital-Artesh Blvu.
City
Sari

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 Makhlough
Street address
Imam sq ; Joybar 3 way
City
Sari
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
Dr Atie Makhlough
Position
Associated professor/Aademic staff of mazandaranl univercity of medical sciences
Other areas of specialty/work
Street address
Imam Khomaini Hospital, Razi Street
City
Sari
Postal code
Phone
+98 15 1226 1700
Fax
+98 15 1226 4044
Email
makhlough_a@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Mazandaran Univercity of Medical Sciences and Health Services
Full name of responsible person
Dr Atie Makhlough
Position
Nephrologist/Associated professor Academic Member of Mazandaran Univercity
Other areas of specialty/work
Street address
Imam Khomaini hospital, Razi St.
City
Sari
Postal code
Phone
+98 15 1226 4047
Fax
Email
makhlough_a@yahoo.com
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Mazandaranl Univercity of Medical Sciences and Health Services

Full name of responsible person
Dr Atie Makhlough

Position
Nephrologist/Associate Professor/Academic staff of mazandaran university of medical sciences

Other areas of specialty/work

Street address
Imam Khomani hospital, Razi St.

City
Sari

Postal code

Phone
+98 15 1226 4047

Fax
+98 15 1226 4044

Email
makhlough_a@yahoo.com

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