Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the effect of Helicobacter Pylori eradication regimens in patients with end stage renal disease

Protocol summary

Summary

Objectives: The aim of this study is to compare the effect of Helicobacter Pylori (HP) eradication regimens in patients with end stage renal disease (ESRD). Design: 120 patients with end stage renal disease and confirmed HP infection using upper endoscopy will be select random and will receive eradication regimens in four groups. Inclusion criteria: Patients with end stage renal disease and helicobacter pylori infection. Exclusion criteria: pregnancy, liver failure, patient with active cancer, recent using of Proton pomp inhibitors, Non steroidal anti inflammatory drugs, bismuth and antibiotics during last four weeks, history of alcohol abuse, cigarette smoking and any drug reactions . Intervention: the patients will be divided to four groups according to 2-week eradication regimens; Group I: RCA (clarithromycin 250 mg-BD, amoxicillin 500 mg-BD, rabeprazole 20 mg-BD), Group II: RCM (clarithromycin 250 mg-BD, metronidazole 500 mg-BD, rabeprazole 20 mg-BD), Group III: RCAM (clarithromycin 250 mg-BD, metronidazole 500 mg-BD, amoxicillin 500 mg-BD, rabeprazole 20 mg-BD) and Group IV: Sequential (rabeprazole 20 mg-BD, first week; amoxicillin 500 mg-BD and second week; clarithromycin 250 mg-BD, metronidazole 500 mg-BD. Main outcome measures: Four weeks after treatment end, Urea Breath Test (UBT) that will be an indicator for eradication of H.P. will perform for all patients and the results will compare in the groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015081123591N1**
Registration date: **2015-09-01, 1394/06/10**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2015-09-01, 1394/06/10

Registrant information

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Peyman Sanjari Pirayvatlou
Name of organization / entity
Golestan University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Golestan university of medical sciences

Expected recruitment start date

2013-03-21, 1392/01/01

Expected recruitment end date

2014-03-21, 1393/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of Helicobacter Pylori eradication regimens in patients with end stage renal disease

Public title

The comparison of the efficacy of four different therapeutic regimens against Hlicobacter pylori infection

in End Stage Renal Disease patients.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: All ESRD patients with confirmed H.pylori infection using Endoscopic gasterodeodenoscopy with complete consciousness of patient about research. Exclusion criteria: Pregnancy, liver failure, patient with active cancer, recent using of Proton pomp inhibitors, Non steroidal anti inflammatory drugs, bismuth and antibiotics during last four weeks, history of alcohol abuse, cigarette smoking and any drug reactions.

Age

No age limit

Gender

Both

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

the patients will be selected among the end stage renal disease individuals with helicobacter pylori in a simple random selection.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Golestan university of medical sciences

Street address

Central organization of Golestan University of Medical sciences, next to Anjirab, Hirkan boulevard

City

Gorgan

Postal code

4918936316

Approval date

2014-03-16, 1392/12/25

Ethics committee reference number

39459212254

Health conditions studied

1

Description of health condition studied

Helicobacter pylori infection

ICD-10 code

B98.0

ICD-10 code description

Helicobacter pylori [H.pylori] as the cause of diseases classified to other chapters

Primary outcomes

1

Description

Helicobacter pylori

Timepoint

4 weeks after finishing of treatment course

Method of measurement

Patients swallow urea labelled with an uncommon isotope, either radioactive carbon-14 or non-radioactive carbon-13. In the subsequent 10–30 minutes, the detection of isotope-labelled carbon dioxide in exhaled breath indicates that the urea was split; this indicates that urease (the enzyme that H. pylori uses to metabolize urea) is present in the stomach, and hence that H. pylori bacteria are present

Secondary outcomes

1

Description

-

Timepoint

-

Method of measurement

-

Intervention groups

1

Description

Intervention group 1: RCA regimen (capsule Clarythromycin 250 mg every 12 hours, capsule Amoxicillin 500 mg every 12 hours, tablet Rabeprazole 20 mg every 12 hours)

Category

Treatment - Drugs

2

Description

Intervention group 3: RCAM regimen (capsule Clarythromycin 250 mg every 12 hours, capsule Amoxicillin 250 mg every 12 hours, tablet Rabeprazole 20 mg every 12 hours, tablet Metronidazole 500 mg every 12 hours)

Category
Treatment - Drugs

3

Description
Intervention group 4: sequential regimen (tablet Rabeprazole 20 mg every 12 hours, first week; capsule Amoxicillin 500 mg every 12 hours and second week; capsule Clarithromycin 250 mg every 12 hours,tablet Metronidazole 500 mg every 12 hours)
Category
Treatment - Drugs

4

Description
Intervention group 2: RCM regimen (capsule Clarythromycin 250 mg every 12 hours, tablet Metronidazole 500 mg every 12 hours, tablet Rabeprazole 20 mg every 12 hours)
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
5th. Azar hospital
Full name of responsible person
Dr. Peyman Sanjari Pirayvatlou
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research of Golestan university of medical sciences
Full name of responsible person
Dr.Mohsen Saeedi
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Grant name
129007
Grant code / Reference number
10506
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for research of Golestan 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
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Person responsible for scientific inquiries

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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