

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 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 pump 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

Name

Peyman Sanjari Pirayvatlou

Name of organization / entity

Golestan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 17 3254 6240

Email address

dr.p.sanjari@gmail.com

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 pump 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

Street address

next to 6th. Azar avenue, 5th. Azar street

City

Gorgan

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

Street address

Central organization of Golestan university of medical sciences, next to Anjirab, Hirkan boulevard

City

Gorgan

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****Name of organization / entity**

Golestan University of Medical Sciences

Full name of responsible person

Dr. Peyman Sanjari Pirayvatlou

Position

Internal Medicine Resident

Other areas of specialty/work**Street address**

Central Organization of Golestan University of Medical Sciences, next to Anjirab, Hirkan boulevard

City

Gorgan

Postal code**Phone**

+98 17 3247 0110

Fax**Email**

dr.p.sanjari@gmail.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Golestan university of medical sciences

Full name of responsible person

Dr. Mohamadreza Seyedmajidi

Position

Gastroenterologist

Other areas of specialty/work**Street address**

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

City

Gorgan

Postal code**Phone**

+98 17 3247 0110

Fax**Email**

mrsmajidi@goums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Golestan University of Medicalsciences

Full name of responsible person

Dr. Peyman Sanjari Pirayvatlou

Position

Internal Medicine Resident

Other areas of specialty/work**Street address**

Central Organization of Golestan University of Medical Sciences, next to Anjirab, Hirkan boulevard

City

Gorgan

Postal code**Phone**

+98 17 3247 0110

Fax**Email**

dr.p.sanjari@gmail.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