Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jul 2026

Comparison the effect of different creatinine clearance levels on helicobacter pylori eradication rate in peptic ulcer patients.

Protocol summary

Summary

The goal of this study is to determine the effect of different creatinine clearance levels on helicobacter pylori(HP) eradication rate in peptic ulcer patients. Not blinded, No placebo-controlled, single center study. Inclusion criteria: Peptic ulcer patients, which have recently been proven by endoscopy and are HP positive, are enrolled. Exclusion criteria: Pregnant women ; patients with cancer ; liver failure; smoking , alcohol consumption ; drug allergy; use of proton pomp inhibitors (PPIs), non steroid anti inflammatory drugs (NSAIDS), bismuth and antibiotics in last 4 weeks. Target sample size is 125 patients. Peptic ulcer patients which are HP positive are divided into five groups according to creatinine clearance. All of them are given standard triple therapy and in creatinine clearance less than 30 milliliter (ml) per minute (ml/min) Clarithromycin and amoxicillin dose is reduced by 50 percent. HP eradication rate is evaluated in the different groups with urease breath test (UBT) 6 weeks after therapy ends. Intervention time is winter 1391 and spring and summer 1392. Study outcome is HP eradication rates in different groups according to creatinine clearance.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013060913609N1**
Registration date: **2013-08-18, 1392/05/27**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-08-18, 1392/05/27

Registrant information

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Mehdi Alimadadi
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Recruitment status

Recruitment complete

Funding source
Vice chancellor for research, Golestan University of Medical Sciences

Expected recruitment start date

2013-01-20, 1391/11/01

Expected recruitment end date

2013-08-23, 1392/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of different creatinine clearance levels on helicobacter pylori eradication rate in peptic ulcer patients.

Public title

The amount of helicobacter pylori eradication in renal failure patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Peptic ulcer patients, which have recently been proven by endoscopy and are HP positive, are enrolled. Exclusion criteria: Pregnant women ;

patients with cancer ; liver failure; smoking , alcohol consumption ; drug allergy; use of proton pomp inhibitors (PPIs), non steroid anti inflammatory drugs (NSAIDS), bismuth and antibiotics in last 4 weeks.

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **125**

Randomization (investigator's opinion)
N/A

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
Ethics committee of Golestan University of Medical Sciences

Street address
High education department of Falsafi, The Shast Kola road, Sari to Gorgan road 5 Kilometer, Gorgan

City
Gorgan

Postal code
4934174515

Approval date
2013-03-17, 1391/12/27

Ethics committee reference number
356191122715

Health conditions studied

1

Description of health condition studied
peptic ulcer

ICD-10 code
K27

ICD-10 code description
gastroduodenal ulcer NOS peptic ulcer NOS

Primary outcomes

1

Description
Helicobacter pylori eradication

Timepoint
Before and 8 weeks after intervention

Method of measurement
Before intervention in antrum sample with rapid urease test and 8 weeks after intervention with urease breath test

Secondary outcomes

1

Description
Creatinine clearance

Timepoint
3 months before the intervention and at the begining and during the intervention.

Method of measurement
According to formula 24 hour urine volume× (urine creatinine/serum creatinine)

Intervention groups

1

Description
Group 1: Capsule omeprazol 20 milligram (mg) twice daily (OSVEH Pharmaceutical Company); Tablet clarithromycin 500 mg twice daily (CHEMIDAROU Pharmaceutical Company); Capsule amoxicillin 1 gram (gr) twice daily (FARABI Pharmaceutical Company) all of them for 2 weeks.

Category
Treatment - Drugs

2

Description
Group 2: Capsule omeprazol 20 milligram (mg) twice daily (OSVEH Pharmaceutical Company); Tablet clarithromycin 500 mg twice daily (CHEMIDAROU Pharmaceutical Company); Capsule amoxicillin 1 gram (gr) twice daily (FARABI Pharmaceutical Company) all of them for 2 weeks.

Category
Treatment - Drugs

3

Description
Group 3: Capsule omeprazol 20 milligram (mg) twice daily (OSVEH Pharmaceutical Company); Tablet clarithromycin 500 mg twice daily (CHEMIDAROU Pharmaceutical Company); Capsule amoxicillin 1 gram (gr) twice daily (FARABI Pharmaceutical Company) all of them for 2 weeks.

Category

Treatment - Drugs

4

Description
Group 4: Capsule omeprazol 20 milligram (mg) twice daily (OSVEH Pharmaceutical Company); Tablet clarithromycin 250 mg twice daily (CHEMIDAROU Pharmaceutical Company); Capsule amoxicillin 500 mg twice daily (FARABI Pharmaceutical Company) all of them for 2 weeks.
Category
Treatment - Drugs

5

Description
Group 5: Capsule omeprazol 20 milligram (mg) twice daily (OSVEH Pharmaceutical Company); Tablet clarithromycin 250 mg twice daily (CHEMIDAROU Pharmaceutical Company); Capsule amoxicillin 500 mg twice daily (FARABI Pharmaceutical Company) all of them for 2 weeks.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
5 Azar Hospital
Full name of responsible person
Mohammad Reza Seyyed Majidi, Gastroenterologist, Assistant professor
Street address
5 Azar Street, Gorgan
City
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Golestan University of Medical Sciences
Full name of responsible person
Kamran Haidari, Research Assistant
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High education department of Falsafi, The Shast Kola road, Sari to Gorgan road 5 Kilometer, Gorgan
City
Gorgan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, 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
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Mehdi Alimadadi
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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