

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 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 pump 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

Name

Mehdi Alimadadi

Name of organization / entity

Golestan University of Medical Sciences

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Iran (Islamic Republic of)

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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 pump 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 beginning and during the intervention.

Method of measurement

According to formula 24 hour urine volumex (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

Gorgan

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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road, Sari to Gorgan road 5 Kilometer, Gorgan

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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

Golestan University of Medical Sciences

Full name of responsible person

Mehdi Alimadadi

Position

Resident of Internal Medicine

Other areas of specialty/work

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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