

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of Azithromycin and Clarithromycin in triple therapy regimens for eradication of helicobacter pylori in hemodialysis patients

Protocol summary

Summary

This study aimed to compare a triple therapy regimen based on change of antibiotic (Azithromycin and Clarithromycin) for the eradication of helicobacter pylori in patients with end stage renal disease under treatment of hemodialysis. In this prospective, randomized, double-blinded trial, thirty nine dialysis patients, aged 17-88 years old, referred to two hemodialysis centers (Valiasr & Beheshti hospitals) in Zanjan were enrolled between March to October 2008. The patients were randomly assigned into one of two groups. The first Group received Omeprazol 20 mg, Amoxycilin 500 mg, and Clarithromycin 500mg twice a day, while the second group received Omeprazol 20mg, Amoxicillin 500mg, and Azithromycin 250mg twice a day for 14 days. The adverse events and compliance with triple therapy were reviewed weekly. Eradication of infection was assessed using UBT and HpSAg eight weeks after therapeutic regimens.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138811223325N1**

Registration date: **2010-04-24, 1389/02/04**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-04-24, 1389/02/04

Registrant information

Name

Majgan Jalalzadeh

Name of organization / entity

Zanjan University Of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Zanjan University of Medical Sciences

Expected recruitment start date

2008-10-22, 1387/08/01

Expected recruitment end date

2009-02-19, 1387/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Azithromycin and Clarithromycin in triple therapy regimens for eradication of helicobacter pylori in hemodialysis patients

Public title

H. Pylori In Hemodialysis Patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Presence of dyspepsia, positive results of H. pylori infection in two out of three diagnostic tests: anti H. pylori serology, H.pylori stool antigen (HpSAg) and Urease Breath Test (UBT) Exclusion criteria: history of previous treatment for H. Pylori, use of any of the investigated antibiotics in the previous six months, allergy to study medications, inability to perform UBT

Age

From **18 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **39**

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**

Zanjan University of Medical Sciences

Street address

Zanjan University of Medical Sciences, Zanjan

City

Zanjan

Postal code**Approval date**

2010-02-23, 1388/12/04

Ethics committee reference number

19/3-304488

Health conditions studied**1****Description of health condition studied**

helicobacter pylori

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**

Adverse events and compliance

Timepoint

one visit a week

Method of measurement

Questionnaire

Secondary outcomes**1****Description**

H pylori eradication

Timepoint

Eight weeks after therapeutic regimen

Method of measurement

UBT

Intervention groups**1****Description**

Omeprazol 20 mg, Amoxicillin 500 mg, and Clarithromycin 500mg twice a day, for 14 days

Category

Treatment - Drugs

2**Description**

Omeprazol 20mg, Amoxicillin 500mg, and Azithromycin 250mg twice a day, for 14 days

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Hemodialysis Center of Zanjan City - Iran

Full name of responsible person

Dr Mojgan Jalalzadeh

Street address

Valiasr Hospital of Zanjan

City

Zanjan

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Zanjan University Of Medical Science

Full name of responsible person

Mr Jafari Anaekoli

Street address

Zanjan, Azadi Square P.C. 45154-11447

City

Zanjan

Grant name**Grant code / Reference number**

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Zanjan Univercity Of Medical Science

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**

Qom Univrecity of Medical Sciences

Full name of responsible person

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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