

# 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)

##### Phone

+98 24 1426 6934

##### Email address

jmojgan@zums.ac.ir

##### 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

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Jamshid Vafaee Manesh

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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*