

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluation of H pylori eradication rate with 14-days levofloxacin, amoxicillin & pantoprazole regimen and its comparison with standard regimen of clarithromycin, amoxicillin & pantoprazole in patients of gastrointestinal clinic

#### Protocol summary

##### Study aim

Determination of H pylori eradication rate with 14-days levofloxacin, amoxicillin & pantoprazole regimen and its comparison with standard regimen of clarithromycin, amoxicillin & pantoprazole in patients of GI clinic (Kerman-2017) and its relation with patients age and sex

##### Design

Urease positive patients are divided randomly into two equal groups (each group 85 patient and totally 170 patient) and each group are treated with one of above-mentioned A or B antibiotic regimens for 14 days

##### Settings and conduct

This study determines the eradication rate of gastric H. pylori infection with two combination triple therapy regimens: A and B, and compare them with each other. Patients aged 18 to 65 with upper abdominal symptoms in gastrointestinal clinic of Kerman University of Medical Sciences in 2017 undergo upper endoscopy if indicated (according to GI disease references) and rapid urease test on gastric mucosa is done for them to evaluate helicobacter pylori infection

##### Participants/Inclusion and exclusion criteria

Exclusion criteria: PPI consumption in 2 wks ago; antibiotic use in 4 wks ago; GI bleeding; allergy to antibiotics; drug intolerance; unresponsiveness to standard clarithromycin regimen (due to ethical consideration) Inclusion criteria: ages between 18 and 65 with epigastric complaints

##### Intervention groups

Regimen A includes levofloxacin, amoxicillin and pantoprazole. Regimen B includes clarithromycin, amoxicillin and pantoprazole. The duration of treatment is 14 days for both regimens

##### Main outcome variables

One month later, stool antigen test will be done to

determine the eradication rate of helicobacter infection.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170803035490N1**

Registration date: **2017-12-04, 1396/09/13**

Registration timing: **registered\_while\_recruiting**

Last update: **2017-12-04, 1396/09/13**

Update count: **0**

##### Registration date

2017-12-04, 1396/09/13

##### Registrant information

##### Name

Masoud Hajmohammadi

##### Name of organization / entity

Kerman University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 34 3132 5709

##### Email address

m.hajmohammadi@kmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

governmental and research fund

##### Expected recruitment start date

2017-03-20, 1395/12/30

##### Expected recruitment end date

2018-03-21, 1397/01/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Evaluation of H pylori eradication rate with 14-days levofloxacin, amoxicillin & pantoprazole regimen and its comparison with standard regimen of clarithromycin, amoxicillin & pantoprazole in patients of gastrointestinal clinic

**Public title**

Gastric Helicobacter pylori infection eradication rate with levofloxacin based regimen and comparison with standard clarithromycin regimen

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Age from 18 to 65 yrs With epigastric problems

**Exclusion criteria:**

PPI consumption in 2 wks ago Antibiotic use in 4 wks ago  
GI bleeding Allergy to antibiotics Drug intolerance  
Unresponsiveness to standard clarithromycin regimen (duo to ethic consideration)

**Age**From **18 years** old to **65 years** old**Gender**

Both

**Phase**

N/A

**Groups that have been masked***No information***Sample size**Target sample size: **170****Randomization (investigator's opinion)**

Randomized

**Randomization description**

Method of randomization : block, Unit of randomization : individual, Tools used in randomization : table of random numbers

**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**

Kerman University of Medical Sciences

**Street address**

University Campus, Haftbagh Highway

**City**

Kerman

**Province**

Kerman

**Postal code**

7616913555

**Approval date**

2016-09-05, 1395/06/15

**Ethics committee reference number**

IR.KMU.AH.REC.1395.42

**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 eradication rate in stomach

**Timepoint**

One month after therapy

**Method of measurement**

Stool antigen test

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

drug side effects

**Timepoint**

during and after intervention

**Method of measurement**

monitoring for side effects

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

Levofloxacin:250 mg po Bid , Amoxicillin:1 gr po Bid,  
Pantoprazole:40 mg po Bid 14 days

**Category**

Treatment - Drugs

**2**

**Description**

Clarithromycin:500 mg po Bid , Amoxicillin:1gr po Bid ,  
Pantoprazole :40 mg po Bid , 14 days

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Besat Clinic 1

**Full name of responsible person**

Dr Bijan Ahmadi

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Tahmasbabad Crossway, Shariati Street

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**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

Dr Abbas Pardakhti

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Vice-Chancellor for Research Building, tahmasbabad  
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**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Kerman University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

empty

**Country of origin**

**Type of organization providing the funding**

Academic

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

Dr Bijan Ahmadi

**Position**

Assistant Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

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**Position**

Resident of Internal Medicine

**Latest degree**

Medical doctor

**Other areas of specialty/work**

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**Fax****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available