

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 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

determine the eradication rate of helicobacter infection.

Study aim

Determination of H pylori eradication rate with 14-days levofloacin, amoxicillin & pantoprazol regimen and its comparison with standard regimen of clarithromycin, amoxicillin & pantoprzol 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 abovementioned 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(duo to ethic 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

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

Street address

Tahmasbabad Crossway, Shariati Street

City

Kerman

Province

Kerman

Postal code

13555 76169

Phone

+98 34 3226 8740

Email

besatclinic@kmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Dr Abbas Pardakhti

Street address

Vice-Chancellor for Research Building, tahmasbabad
Crossway, Shariati Streeti

City

Kerman

Province

Kerman

Postal code

7616913555

Phone

+98 34 3226 3815

Email

kmu_research@yhoo.com

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

Street address

Afzalipor Hospital, Emam Highway

City

Kerman

Province

Kerman

Postal code

7616913911

Phone

+98 34 3132 8000

Fax

Email

Ay_bijan@yahoo.com

Web page address

Person responsible for scientific 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

Internal Medicine

Street address

Afzalipor Hospita, Emam Highway

City

Kerman

Province

Kerman

Postal code

7616913911

Phone

+98 34 3132 8000

Fax

+98 34 3325 7770

Email

Ay_bijan@yahoo.com

Web page address

+98 34 3325 7770

Email

Masoudjmd@yahoo.com

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Kerman University of Medical Sciences

Full name of responsible person

Dr Masoud Hajmohammadi

Position

Resident of Internal Medicine

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

Street address

Afzalipor Hospital, Emam Highway,

City

Kerman

Province

Kerman

Postal code

7616913911

Phone

+98 34 3132 8000

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