

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 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 (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

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Name of organization / entity

Kerman University of Medical Sciences

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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)

AgeFrom **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 committees1**Ethics committee****Name of ethics committee**

Kerman University of Medical Sciences

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University Campus, Haftbagh Highway

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7616913555

Approval date

2016-09-05, 1395/06/15

Ethics committee reference number

IR.KMU.AH.REC.1395.42

Health conditions studied1**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 outcomes1**Description**

Helicobacter pylori eradication rate in stomach

Timepoint

One month after therapy

Method of measurement

Stool antigen test

Secondary outcomes1**Description**

drug side effects

Timepoint

during and after intervention

Method of measurement

monitoring for side effects

Intervention groups1**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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

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Full name of responsible person

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Position

Assistant Professor

Latest degree

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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