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

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 between18 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

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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)
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 Univercity of Medical Sciences
Street address
Univercity Campus, Haftbagh Highway
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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
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Sponsors / Funding sources

1

Sponsor
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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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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