Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison between levofluxain and clarithromycin treatment in helicobacter pylori eradication

Protocol summary

Summary

Helicobacter pylori infection is the major cause of chronic gastritis ,peptic ulcer,gastric adenocarcinoma and gastric lymphoma(MALT).helicobacter eradication prevents recurrence of peptic ulcer and reduces the risk of gastric cancer.standard triple therapy is the first line for eradication of helicobacter pylori that is composed of a PPi or H2b with one or two antibiotic(clarythromycine,amoxicillin,metronidazole) For 7-14 days.but resistance to antibiotics reduces the efficacy of therapeutic regimen.resistance to clarythromycine is increasing worldwide,and is considered to be a primary factor reducing efficacy against h.pylori. Several studies from iran was published that reported the resistance rate to clarithromycin is between 16-30/1%. Some studies have shown excellent eradication rates(85-95%) with triple therapy based on levofloxacin as .levofluxacin is safe and telorated well by patient.so we decided to design a study to compare standard trple therapy based on clarithromycine with triple therapy based on levofloxacin in our area.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015030421328N1**
Registration date: **2015-03-26, 1394/01/06**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-03-26, 1394/01/06

Registrant information

Name

Shahriyar Savadkoohi

Name of organization / entity

Babol University Of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

vice-chancellor Of Research Babol University Of Medical Science

Expected recruitment start date

2014-10-22, 1393/07/30

Expected recruitment end date

2014-12-21, 1393/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between levofluxain and clarithromycin treatment in helicobacter pylori eradication

Public title

Comparison between levofluxain and clarithromycin treatment in helicobacter pylori eradication

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:complaint of dyspepsia Exclusion criteria:using ppi or h2b during recent 4weeks,past history of gastric surgery,past history of gastric cancer,pregnancy,comorbid diseases.

Age

From **18 years** old to **80 years** old

Gender
Both

Phase
1
Groups that have been masked
No information
Sample size
Target sample size: **80**
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
Babol University Of Medical Sciences
Street address
Daneshgah Sq - Ganjafrooz St-
City
Babol
Postal code
4717641367
Approval date
2014-03-08, 1392/12/17
Ethics committee reference number
3810 /30/پ/ژ

Health conditions studied

1

Description of health condition studied
Helicobacter pylori
ICD-10 code
K20-K31
ICD-10 code description
Diseases of oesophagus, stomach and duodenum

Primary outcomes

1

Description
eradication rate of helicobacter pylori
Timepoint
4 weeks after the end of the intervention
Method of measurement
Stool Ag

Secondary outcomes

1

Description
Eradication rate of HP in male and female
Timepoint
4 weeks after intervention
Method of measurement
Stool Ag

2

Description
Endoscopic findings
Timepoint
Before the intervention
Method of measurement
Endoscopic

Intervention groups

1

Description
First group: Omeprazole 20 mg daily, Clarithromycin 500 mg daily Ampxicillin 1 gr BD
Category
Treatment - Drugs

2

Description
Second group: Omeprazole 20 mg daily, levofluxacin 500 mg daily Ampxicillin 1 gr BD
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ruhani Hospital
Full name of responsible person
Dr Shahriar savadkoohi
Street address
Department of Internal Medicine, Ruhani Hospital, Daneshgah Square, Ganjafrooz Avenue Babol
City
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice-chancellor Of Research, Daneshgah Square, Ganjafrooz Avenue
Full name of responsible person
Ali Akbar Moghadamnia
Street address
Babol University of Medical Sciences
City
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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
Vice-chancellor Of Research, Daneshgah Square, Ganjafrooz Avenue

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
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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