

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Comparison between levofloxacin 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 (clarithromycin, amoxicillin, metronidazole) for 7-14 days. But resistance to antibiotics reduces the efficacy of therapeutic regimen. Resistance to clarithromycin is increasing worldwide, and is considered to be a primary factor reducing efficacy against h. pylori. Several studies from Iran were 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 .levofloxacin is safe and tolerated well by patient. So we decided to design a study to compare standard triple therapy based on clarithromycin 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 Savadkoobi

Name of organization / entity

Babol University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 3223 8284

Email address

sh.soleimani@mubabol.ac.ir

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 levofloxacin and clarithromycin treatment in helicobacter pylori eradication

Public title

Comparison between levofloxacin 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 4 weeks, 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/ج

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 Ampicillin 1 gr BD

Category

Treatment - Drugs

2**Description**

Second group: Omeprazole 20 mg daily, levofloxacin 500 mg daily Ampicillin 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

Babol

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

Babol

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**

Babol University Of Medical Sciences

Full name of responsible person

Dr Narges sadeghi

Position

Resident of Internal Medicine

Other areas of specialty/work**Street address**

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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Full name of responsible person

Dr Javad Shokri Shirvani

Position

Professor of Gastroenterology

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Full name of responsible person

Narges Sadeghi

Position

Resident of Internal Medicine

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Fax**Email****Web page address****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