

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of Levofloxacin- containing and Clarithromycin -containing Sequential Therapies for Helicobacter pylori Eradication in Iran: A Randomized Clinical Trial

Protocol summary

Summary

This randomized clinical trial will be done on 182 patients at gastrointestinal clinic of Rasoul Akram Hospital, whose duodenal ulcer, gastric ulcer and/or erosions is diagnosed by endoscopy and H.pylori infection is detected by rapid urease test or histological Geimsa staining on biopsied specimens during endoscopy. The patients are randomly enrolled to either of the two groups using a computer-generated randomization: 91 patients receive (group A): esomeprazole (40 mg/b.i.d.) and amoxicillin (1000 mg/b.i.d.) for first 5 days and esomeprazole (40 mg/b.i.d.) and tinidazole and clarithromycin (each 500 mg/b.i.d.) for second 5 days. 91 patients receive (group B): esomeprazole (40 mg/b.i.d.) and amoxicillin (1000 mg/b.i.d.) for first 5 days and esomeprazole (40 mg/b.i.d.) and tinidazole and levofloxacin (each 500 mg/b.i.d.) for second 5 days. Patients record side effects of medications (such as; Bitter taste, drymouth, diarrhea, constipation, headache, nausea, vomiting, and abdominal pain) on a daily basis and are advised to call the doctors if side effects are severe. All patients are visited 2 weeks after treatment. They are also asked about drug side effects and their compliance to medication according to remaining pill count at the end of the treatment. Then, they will be advised for 4 weeks consumption of PPI and for the last 4 weeks without any PPI and/or antibiotics consumption. Ten weeks after starting the treatment, H. pylori eradication is assessed by 14C-urea breath test (UBT). Treatment efficacy in each group is determined according to the Intention-To-Treat (ITT) and Per-Protocol (PP) eradication rates analysis. Chi square test is used for comparing proportion between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015030820178N2**

Registration date: **2015-03-26, 1394/01/06**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-03-26, 1394/01/06

Registrant information

Name

Marjan Mokhtare

Name of organization / entity

Iran University of Medical sciences, Rasoul Akram Hospital, Colorectal Research Center

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Iran University of Medical Sciences

Expected recruitment start date

2015-01-21, 1393/11/01

Expected recruitment end date

2015-12-22, 1394/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Levofloxacin- containing and Clarithromycin -containing Sequential Therapies for Helicobacter pylori Eradication in Iran: A Randomized Clinical Trial

Public title

Efficacy of Levofloxacin- containing versus Clarithromycin -containing Sequential Therapies in Helicobacter pylori Eradication

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:age more than18 years,patients with endoscopically confirmed peptic ulcer or gastric/duodenal erosions and H. pylori infection documentation by antral biopsy (Giemsa staining) and/or rapid urease test (RUT). exclusion criteria:pregnancy, breast-feeding, previous history of helicobacter pylori eradication,significant underlying diseases such as liver, cardiac, pulmonary or renal diseases, neoplasms, coagulopathy, history of gastric surgery, taking antibiotics,proton pump inhibior and /or histamin2 receptor antagonist during the previous2 weeks,concomitant use of anticoagulant and/or corticosteroid, and previous history of allergic reaction to any medications used in this study.

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **182**

Randomization (investigator's opinion)

Randomized

Randomization description

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

Iran University of Medical Sciences Ethics Committee

Street address

Iran University of Medical Sciences,West Shahid

Hemmat Highway,Intersection of Chamran and Sheikh Fazlollah Noori,Tehran Iran

City

Tehran

Postal code

Approval date

2015-02-28, 1393/12/09

Ethics committee reference number

105/5840/93/3

Health conditions studied

1

Description of health condition studied

gastric ulcer or erosion-deudenal ulcer or erosion

ICD-10 code

k25-K26 -B

ICD-10 code description

Gastric ulcer-Duodenal ulcer- Helicobacter pylori [H.pylori] as the cause of diseases classified to other chapters

Primary outcomes

1

Description

Helicobacter pylori eradication rate

Timepoint

Ten weeks after starting treatment

Method of measurement

urea breath test(UBT)

Secondary outcomes

1

Description

Drug adverse effect rate

Timepoint

Two weeks after starting treatment

Method of measurement

Data gathering sheet

2

Description

Patient compliance rate

Timepoint

Two weeks after starting treatment

Method of measurement

Remained pill count

Intervention groups

1

Description

Group A:10 days of sequential therapy (esomeprazole 40 mg twice daily, amoxicillin 1g twice daily for 5 days

followed by esomeprazole 40 mg twice daily, levofloxacin 500 mg twice daily, and tinidazole 500 mg twice daily for 5 more days

Category

Treatment - Drugs

2

Description

Group B:10 days of sequential therapy (esomeprazole 40 mg twice daily, amoxicillin 1g twice daily for 5 days followed by esomeprazole 40 mg twice daily, clarithromycin 500 mg twice daily, and tinidazole 500 mg twice daily for 5 more days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasaul Akram Hospital

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences,Rasoul Akram Hospital,Colorectal Research Center

Full name of responsible person

Shahram Agah

Street address

Sattarkhan Street, Niayesh Street

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Iran University of Medical Sciences,Rasoul Akram Hospital,Colorectal Research Center

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

Rasaul Akram Hospital

Full name of responsible person

Mehdi Nikkhah

Position

Fellow of Gastroenterology and hepatology

Other areas of specialty/work

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

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Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty