

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 2026

Effect of helicobacter pylori eradication regimen versus standard treatment on gastro-esophageal reflux symptoms in patients with antral gastritis: a triple blinded randomized controlled trial

Protocol summary

Summary

Objectives: To investigate the effect of helicobacter pylori eradication regimen versus standard treatment on gastro-esophageal reflux symptoms in patients with antral gastritis **Design:** a triple blinded randomized controlled trial **Setting and conduct:** We will recruit 162 patients with heartburn and other symptoms of gastro-esophageal reflux disease who refer to Gastroenterology clinic. **Participants including major eligibility criteria:** The patient's with one of the following symptoms: gastro-esophageal reflux, dysphagia; heartburn; nausea; chest pain; and nuisance conditions that lead to awakening the patient will be included if they have endoscopic detection of gastritis and H. pylori infection in biopsy of gastric mucosa. **Intervention:** The control group will received standard treatment for reflux including Omeprazole 20 mg BID for two weeks. The intervention group will receive eradication treatment including Omeprazole 20 mg BID, Clarithromycin 500 mg BID, and Amoxicillin 1000 mg BID for two weeks. **Main outcome measures (variables):** The frequency and severity of reflux will be assessed four weeks after intervention via history taking of heartburn, regurgitation, nausea, dysphagia, chest pain, and nocturnal

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201202229014N2**
Registration date: **2012-05-28, 1391/03/08**
Registration timing: **na**

Last update:

Update count: **0**

Registration date

2012-05-28, 1391/03/08

Registrant information

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Name of organization / entity

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Recruitment status

Not enough for processing

Funding source

Vic-chancellor of Research and Technology, Hamadan
University of Medical Sciences

Expected recruitment start date

2012-05-21, 1391/03/01

Expected recruitment end date

empty

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of helicobacter pylori eradication regimen versus standard treatment on gastro-esophageal reflux symptoms in patients with antral gastritis: a triple blinded randomized controlled trial

Public title

Effect of helicobacter pylori eradication regimen versus standard treatment on gastro-esophageal reflux symptoms in patients with antral gastritis

Purpose

Treatment

Inclusion/Exclusion criteria

The patient's with one of the following symptoms: gastro-esophageal reflux, dysphagia; heartburn; nausea; chest pain; and nuisance conditions that lead to awakening the patient will be included if they have endoscopic detection of gastritis and H. pylori infection in biopsy of gastric mucosa. The patents with following characteristics will be excluded from the study: simultaneous gastritis of fundus and antrum (pangastritis); gastric ulcer; duodenal ulcer; surgical history of esophagus, stomach, or duodenum; and history of using NSAIDs.

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 162

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Local Human Subject Review board

Street address

Hamadan University of Medical Sciences, Shaheed Fahmideh Ave

City

Hamadan

Postal code

6517838695

Approval date

2012-05-16, 1391/02/27

Ethics committee reference number

D/P/16/35/9/633

Health conditions studied

1

Description of health condition studied

Gastroesophageal reflux

ICD-10 code

K21.9

ICD-10 code description

Gastro-oesophageal reflux disease without oesophagitis

Primary outcomes

1

Description

Frequency and severity of reflux

Timepoint

After four weeks

Method of measurement

History taking of heartburn, regurgitation, nausea, dysphagia, chest pain, and nocturnal

Secondary outcomes

1

Description

Abdominal pain and diarrhea

Timepoint

Two weeks later

Method of measurement

History taking

Intervention groups

1

Description

Intervention group will receive eradication treatment including Omeprazole 20 mg BID, Clarithromycin 500 mg BID, and Amoxicillin 1000 mg BID for two weeks

Category

Treatment - Drugs

2

Description

Control group will receive standard treatment for reflux including Omeprazole 20 mg BID for two weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Gastroenterology subspecialty clinic of Shaheed Beheshti Hospital and private clinic

Full name of responsible person

Dr Ali Reza khalilian

Street address

Gastroenterology subspecialty clinic, Shaheed
Beheshti Hospital, Eram Boulevard

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vic-chancellor of Research and Technology, Hamadan
University of Medical Sciences

Full name of responsible person

Dr Ahmad Tavailani

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Vic-chancellor of Research and Technology, Hamadan
University of Medical Sciences, Shaheed Fahmideh
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Grant name

از محل يك درصد بودجه طرح هاي تحقيقاتي دانشگاه

Grant code / Reference number

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

Yes

Title of funding source

Vic-chancellor of Research and Technology, Hamadan
University of Medical Sciences

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

Research Center for Health Sciences and Department
of Epidemiology & Biostatistics

Full name of responsible person

Dr Jalal Poorolajal

Position

MD, PhD, Assistant Professor of Epidemiology

Other areas of specialty/work

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Other areas of specialty/work

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Person responsible for updating data

Contact

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