Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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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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 Tavilani

Street address

Vic-chancellor of Research and Technology, Hamadan University of Medical Sciences, Shaheed Fahmideh Ave.

City

Hamadan

Grant name

از محل يك درصد بودجه طرح‌هاي 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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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