Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

comparison of Azithromycin and Clarithromycin in H pylori eradication

Protocol summary

Summary

The objective of this study was to compare efficacy of standard triple therapy containing Clarithromycin with triple therapy containing Azithromycin in H pylori eradication. 150 patients were allocated in two groups to receive either a ten-day course of Clarithromycin 500 mg, Amoxicillin 1 gr, Omeprazole 20 mg, all twice daily or Azithromycin (250 mg bid in the first 4 days and then 250 mg daily), Amoxicillin 500 mg, and Omeprazole 20 mg both twice a day. Then all patients received thirty days of Famotidin. After treatment period urease breath test was done for all patients who have completed the course. Response to treatment and possible side effects are recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138809052777N1**
Registration date: **2010-01-13, 1388/10/23**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2010-01-13, 1388/10/23

Registrant information

Name
Seyed Saeid Sarkeshikian
Name of organization / entity
Qom University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 25 1291 9365
Email address
s-sarkeshikian@muq.ac.ir

Recruitment status

Recruitment complete

Funding source

Qom University of Medical Sciences

Expected recruitment start date

2008-12-14, 1387/09/24

Expected recruitment end date

2009-12-14, 1388/09/23

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison of Azithromycin and Clarithromycin in H pylori eradication

Public title

comparison of Azithromycin and Clarithromycin in H pylori eradication

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: H pylori positive patients with endoscopically documented peptic ulcer disease, presence of erosive gastritis or duodenitis or patients with normal endoscopy but first degree relative with gastric cancer Exclusion criteria: age less than eighteen years old, gastric outlet obstructionT, history of allergy to penicillin derivatives

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee Of Qom Medical University

Street address

Qom Medical University, Saheli street

City

Qom

Postal code

Approval date

2006-08-17, 1385/05/26

Ethics committee reference number

34/25571/ پ

Health conditions studied

1

Description of health condition studied

Helicobacter pylori infection

ICD-10 code

B99

ICD-10 code description

Other and unspecified infectious diseases

Primary outcomes

1

Description

eradication of helicobacter pylori infection

Timepoint

after termination of 40 days course of treatment

Method of measurement

urease breath test

Secondary outcomes

empty

Intervention groups

1

Description

Azithromycin 250 mg/ bid /orally for 4 days and 250 mg/ daily/oral for additional 6 days, Amoxicillin 1 gr/bid/orally, Omeprazole 20 mg/bid/orally before meal both for 10 days

Category

Treatment - Drugs

2

Description

Clarithromycin 500 mg/bid/orally, Amoxicillin 1 gr/bid/orally and Omeprazole 20 mg/bid/orally before meal, for 10 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Gasterointestinal clinics of Qom University of Medical Sciences

Full name of responsible person

Seyed Saeid Sarkeshikian

Street address

no.31, 8th Alley, Jomhoori Boulvard,

City

Qom

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Division of Qom University of Medical Sciences

Full name of responsible person

Darabi

Street address

Saheli street,Qom Medical University

City

Qom

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Research Division of Qom 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

Qom University of Medical Sciences

Full name of responsible person

Seyed Saeid Sarkeshikian

Position

Assotiate professor/gasteroenterologist

Other areas of specialty/work

Street address

No. 31, 8th alley, Jomhoori Blvd

City

Qom

Postal code

3716687361

Phone

+98 25 1291 9365

Fax

+98 25 1292 0478

Email

s-sarkeshikian@muq.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Qom Medical University

Full name of responsible person

Seyed Saeid Sarkeshikian

Position

Assotiate professor/gasteroenterologist

Other areas of specialty/work

Street address

No. 31, 8th alley, Jomhoori Blvd

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+98 25 1291 9365

Fax

+98 25 1292 0478

Email

s-sarkeshikian@muq.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Qom University of Medical Sciences

Full name of responsible person

Seyed Saeid Sarkeshikian

Position

Assotiate proffessor/Gastroenterologist

Other areas of specialty/work

Street address

Jomhoori Boulvard, Jomhoori 8,no: 31

City

Qom

Postal code

Phone

+98 25 1291 9365

Fax

Email

s-sarkeshikian@muq.ac.ir

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