

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Effectiveness of Clarithromycin Based and Levofloxacin Based Quadruple Therapy in Combination with Atorvastatin for Helicobacter Pylori Eradication

Protocol summary

Study aim

Comparison of clarithromycin based and levofloxacin based quadruple therapy in combination with atorvastatin for Helicobacter pylori eradication

Design

Randomized clinical trial, with two arm parallel group of 200 patients, will be enrolled between October 2020 and March 2021.

Settings and conduct

In this research, 200 eligible patients need to Helicobacter pylori eradication referring to Qom hospital will be selected. Then, patients by block randomization will be divided randomly into two interventions groups. The first intervention group will receive clarithromycin based quadruple therapy and second intervention group will receive levofloxacin based quadruple therapy.

Participants/Inclusion and exclusion criteria

Inclusion criteria: aged between 18-75, need to Helicobacter pylori eradicate

Intervention groups

Intervention group: Pantoprazole 40 tablet, Octover company, orally, twice a day + Atorvastatin 40 tablet, orally, once a day + Bismuth 500 tablet, orally, four times a day + Amoxicillin 1 g capsule, orally, twice a day + Clarithromycin 500 tablet (Ferromilide, Octover company), orally, twice a day, for 14 days and control group: Pantoprazole 40 tablet, Octover company, orally, twice a day + Atorvastatin 40 tablet, orally, once a day + Bismuth 500 tablet, orally, four times a day + Amoxicillin 1 g capsule, orally, twice a day + Levofloxacin 500 tablet, Abidi company, orally, once daily for 14 days

Main outcome variables

Helicobacter pylori eradication

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200929048884N1**

Registration date: **2020-10-05, 1399/07/14**

Registration timing: **prospective**

Last update: **2020-10-05, 1399/07/14**

Update count: **0**

Registration date

2020-10-05, 1399/07/14

Registrant information

Name

Javad Khodadadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 25 3261 7638

Email address

jkhodadadi@muq.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-11, 1399/07/20

Expected recruitment end date

2021-03-10, 1399/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of Clarithromycin Based and Levofloxacin

Based Quadruple Therapy in Combination with Atorvastatin for Helicobacter Pylori Eradication

Public title

Clarithromycin Based and Levofloxacin Based Quadruple Therapy in Helicobacter Pylori Eradication

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Aged between 18-75 Need to Helicobacter pylori eradicate

Exclusion criteria:

Receive previous treatment to eradicate Helicobacter pylori History of allergies to the drugs used in the study

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **200**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients will be assigned to 2 groups of interventions by block randomization. For this purpose blocks of size 4 will be used. 50 blocks will include. To hide the random allocation, the numbered dark envelopes will be used, in which the group name is specified in the random sequence generated. Then, according to the order of entering samples, for the first patient the envelope number one is opened and the group will be identified until the end

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

Ethics committee of Qom University of Medical Sciences

Street address

No. 83, 4th alley, 1.1 alley, Safashahr Blvd

City

Qom

Province

Ghorm

Postal code

3716987366

Approval date

2020-04-28, 1399/02/09

Ethics committee reference number

IR.MUQ.REC.1399.082

Health conditions studied

1

Description of health condition studied

Helicobacter pylori infection

ICD-10 code

B96.81

ICD-10 code description

Helicobacter pylori [H. pylori] as the cause of diseases classified elsewhere

Primary outcomes

1

Description

Helicobacter pylori eradication

Timepoint

One month after the end of treatment

Method of measurement

Stool antigen test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Pentoprazole 40 tablet, Octover company, orally, twice a day + Atorvastatin 40 tablet, orally, once a day + Bismuth 500 tablet, orally, four times a day + Amoxicillin 1 g capsule , orally, twice a day + Clarithromycin 500 tablet (Ferromilide, Octover company), orally, twice a day, for 14 days

Category

Treatment - Drugs

2

Description

Control group: Pentoprazole 40 tablet, Octover company, orally, twice a day + Atorvastatin 40 tablet, orally, once a day + Bismuth 500 tablet, orally, four times a day + Amoxicillin 1 g capsule , orally, twice a day + Levofloxacin 500 tablet, Abidi company, orally, once daily for 14 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hosbital

Full name of responsible person

Ahmad Hormati

Street address

Shahid Beheshti Hospital, Shahid Beheshti Blvd,
Azadegan Square.

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2

Recruitment center

Name of recruitment center

Kamkar Hospital

Full name of responsible person

Javad Khodadadi

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Kamkar Hospital, 19 Day Street, Qom

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jkhodadadi@muq.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ghoum University of Medical Sciences

Full name of responsible person

Ehsan Sharifipour

Street address

No. 83, 4th alley, 1.1 alley, Safashahr Blvd

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research@muq.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Ghoum University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Ghoum University of Medical Sciences

Full name of responsible person

Javad Khodadadi

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Infectious diseases

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Ghoum University of Medical Sciences

Full name of responsible person

Javad Khodadadi

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

Ghoum University of Medical Sciences

Full name of responsible person

Javad Khodadadi

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Infectious diseases

Street address

Kamkar Hospital, 19 Dey Street, Qom

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

The data are specific to this study

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available