# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 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: 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 and 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

**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**
Ghoum
**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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3719964797
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hormatia@muq.ac.ir

**2**

**Recruitment center**
**Name of recruitment center**
Kamkar Hospital
**Full name of responsible person**
Javad Khodadadi
**Street address**
Kamkar Hospital, 19 Day Street, Qom
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**Postal code**
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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
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No. 83, 4th alley, 1.1 alley, Safashahr Blvd
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**Province**
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**Postal code**
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**Phone**
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**Email**
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
**Street address**
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## Person responsible for scientific inquiries

**Contact**
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**Full name of responsible person**
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**Position**
Associate Professor
**Latest degree**
Specialist
**Other areas of specialty/work**
Infectious diseases

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## Person responsible for updating data

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**Latest degree**
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**Other areas of specialty/work**
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**Fax**
**Email**
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## 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