

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparative evaluation of sequential therapy versus triple therapy and concomitant four-drug therapy for eradication of helicobacter pylori infection in children from 5 to 15 years old

#### Protocol summary

##### Summary

The aim of this study is to compare the evaluation of sequential therapy versus triple therapy and concomitant four drug therapy for eradication of *Helicobacter pylori* infection in children with gastrointestinal disorders. Inclusion criteria will be included: patients with digestive disorders such as recurrent abdominal pain; gastrointestinal bleeding and dyspepsia. Exclusion criteria will be included: having a history of taking medications such as antibiotics; bismuth; proton pump inhibitors; Histamine receptor antagonists and non steroid anti inflammatory drugs in the last 4 weeks. The study population will be included all children from 5 to 15 years old with gastrointestinal disorders. The sample size will be 120 patients. Intervention and its time will be included: treatment in group A with Omeprazole plus Amoxicillin plus Clarithromycin over 10 days, treatment in group B with Omeprazole plus Amoxicillin in the first 5 days and then Omeprazole plus Metronidazole plus Clarithromycin over the next 5 days and treatment in group C with Omeprazole plus Amoxicillin plus Clarithromycin plus Metronidazole over 10 days. The primary outcome variables will be included: *Helicobacter pylori* in the corpus specimen, Histopathology of stomach biopsy, *Helicobacter pylori* in anther sample, rapid urease test and *Helicobacter pylori* stool antigen.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017062234698N1**

Registration date: **2017-09-06, 1396/06/15**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2017-09-06, 1396/06/15

##### Registrant information

###### Name

Behrooz Kamani

###### Name of organization / entity

Qazvin University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 28 3332 8709

###### Email address

b.kamani@qums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Qazvin University of Medical Sciences

##### Expected recruitment start date

2017-09-23, 1396/07/01

##### Expected recruitment end date

2019-02-20, 1397/12/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparative evaluation of sequential therapy versus triple therapy and concomitant four-drug therapy for eradication of *helicobacter pylori* infection in children from 5 to 15 years old

##### Public title

Drug therapy of *Helicobacter pylori* infection

##### Purpose

Treatment

### **Inclusion/Exclusion criteria**

Inclusion criteria: patients with digestive disorders such as recurrent abdominal pain; gastrointestinal bleeding and dyspepsia. Exclusion criteria: having a history of taking medications such as antibiotics; bismuth; proton pump inhibitors; Histamine receptor antagonists and non steroid anti inflammatory drugs in the last 4 weeks.

### **Age**

From **5 years** old to **15 years** old

### **Gender**

Both

### **Phase**

N/A

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **120**

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

### **Blinding (investigator's opinion)**

Not blinded

### **Blinding description**

### **Placebo**

Not used

### **Assignment**

Factorial

### **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Qazvin University of Medical Sciences

##### **Street address**

Shahid Bahonar Blvd., Qazvin

##### **City**

Qazvin

##### **Postal code**

59811-34197

##### **Approval date**

2017-06-21, 1396/03/31

##### **Ethics committee reference number**

IR.QUMS.REC.1396.118

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Helicobacter pylori infection

#### **ICD-10 code**

B98.0

#### **ICD-10 code description**

Helicobacter pylori [H.pylori] as the cause of diseases classified to other chapters

## **Primary outcomes**

### 1

#### **Description**

Helicobacter pylori in the corpus specimen

#### **Timepoint**

Four weeks after the last day of treatment

#### **Method of measurement**

Standard protocol

### 2

#### **Description**

Histopathology of stomach biopsy

#### **Timepoint**

Four weeks after the last day of treatment

#### **Method of measurement**

Standard protocol

### 3

#### **Description**

Helicobacter pylori in another sample

#### **Timepoint**

Four weeks after the last day of treatment

#### **Method of measurement**

Standard protocol

### 4

#### **Description**

Rapid urease test

#### **Timepoint**

Four weeks after the last day of treatment

#### **Method of measurement**

Standard protocol

### 5

#### **Description**

Helicobacter pylori stool antigen

#### **Timepoint**

Four weeks after the last day of treatment

#### **Method of measurement**

Standard protocol

## **Secondary outcomes**

### 1

#### **Description**

Body mass index

#### **Timepoint**

Four weeks after the last day of treatment

#### **Method of measurement**

Body mass index formula

## Intervention groups

### 1

#### Description

Group A: Omeprazole plus Amoxicillin plus Clarithromycin over ten days

#### Category

Treatment - Drugs

### 2

#### Description

Group B: Omeprazole plus Amoxicillin in the first five days and then Omeprazole plus Metronidazole plus Clarithromycin over the next five days

#### Category

Treatment - Drugs

### 3

#### Description

Group C: Omeprazole plus Amoxicillin plus Clarithromycin plus Metronidazole over ten days

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Quds Hospital

##### Full name of responsible person

Behrooz Kamani

##### Street address

Quds Hospital, Quds Square, Shahid Beheshti Blvd., Qazvin

##### City

Qazvin

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Qazvin University of Medical Sciences

##### Full name of responsible person

Amir Peymani

##### Street address

Qazvin University of Medical Sciences, Shahid Bahonar Blvd., Qazvin

##### City

Qazvin

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Qazvin 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

Qazvin University of Medical Sciences

##### Full name of responsible person

Rita Baqerian

##### Position

Postdoctoral

##### Other areas of specialty/work

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md.yar88@yahoo.com

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<http://hosgods.qums.ac.ir/Portal>

## Person responsible for scientific inquiries

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M.D.

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General Physician

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**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*