Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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

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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 anther 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
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Full name of responsible person
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Sponsors / Funding sources

1

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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

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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