

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Comparison of sequential and standard therapy in Helicobacter pylori eradication in children

Protocol summary

Summary

Objectives: Purpose of this study is to introduce a more successful therapy for Helicobacter pylori infection in children by comparing sequential and standard therapy. Study design: uni-center, randomized controlled trial without placebo control, Participants: Sixty children referred to endoscopy ward in Children's Medical Center for investigation of Helicobacter pylori infection Inclusion criteria: 1- Gastrointestinal symptoms 2- Helicobacter pylori infection documented by pathology or rapid urease test 3- Age above 2 years Exclusion criteria: 1- Drug consumption including acid Suppressor drugs and antibiotics during last 4 weeks 2- Hypersensitivity to antibiotics Intervention: After completing the questionnaire about patient's data and gastrointestinal symptoms; all the patients which have Helicobacter pylori infection will be randomized to group 1 (intervention, sequential therapy) and group 2 (control, standard therapy). The patients number in each group approximately is 30. Group 1 will receive omeprazole plus amoxicillin given for the first 5 days followed by a triple therapy including omeprazole, clarithromycin and metronidazole for the remaining 5 days. Group 2 will receive triple therapy by omeprazole plus amoxicillin and metronidazole for 10 days. Treatment continues in both groups by omeprazole until 1 month from initiation of therapy. Main outcome measures: One month after cessation of therapy, Helicobacter pylori stool antigen test will be performed to determine Helicobacter pylori eradication.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013122515929N1**

Registration date: **2014-03-13, 1392/12/22**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-03-13, 1392/12/22

Registrant information

Name

Parisa Rashtian

Name of organization / entity

Children's Medical Center, Tehran University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 21 6691 1029

Email address

p-rashtian@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2014-02-19, 1392/11/30

Expected recruitment end date

2014-08-22, 1393/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of sequential and standard therapy in Helicobacter pylori eradication in children

Public title

Efficacy of sequential and standard therapy on Helicobacter pylori eradication in children

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1- Gastrointestinal symptoms including epigastric tenderness, abdominal pain without reason or at night, pain increase after feeding, early satiety, weight loss without reason, recurrent vomiting, iron deficiency anemia without reason 2- Helicobacter pylori infection documented by pathology or rapid urease test 3- Age below 14 and above 2 years Exclusion criteria: 1- Drug consumption including proton pump inhibitor, histamine blockers, bismuth containing drugs and antibiotics during last 4 weeks 2- History of gastric surgery 3- Hypersensitivity to antibiotics 4- Previous known underlying diseases including renal failure or endocrine diseases

Age

From **2 years** old to **14 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

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 Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Ghods Street, Keshavarz Boulevard

City

Tehran

Postal code

14155/6447

Approval date

2012-05-17, 1391/02/28

Ethics committee reference number

1007/11/ρ

Health conditions studied

1

Description of health condition studied

Helicobacter pylori

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 eradication

Timepoint

Before intervention and 2 months after intervention (1 month after cessation of treatment)

Method of measurement

Pathology or rapid urease test (Baharafshan Co.) on the specimen taken during endoscopy before treatment and fecal antigen test of Helicobacter pylori (G.E.N.E.S.I.S , UK) after treatment

Secondary outcomes

1

Description

Treatment Side Effects

Timepoint

2 Weeks After Beginning of Treatment

Method of measurement

Questionnaire

2

Description

Endoscopic presentations of Helicobacter pylori

Timepoint

Before intervention

Method of measurement

Endoscopic view recorded in questionnaire

Intervention groups

1

Description

Intervention 1: The sequential regimen is a dual therapy including omeprazole (Dr. Abidi Co.) 1mg/Kg plus amoxicillin (Farabi Co.) 25mg/Kg (both twice daily) given for the first 5 days followed by a triple therapy including omeprazole (1mg/Kg), clarithromycin (Chemidarou Co.) 7.5mg/Kg and metronidazole (Tehranshimi Co.) 10mg/Kg (all twice daily) for the remaining 5 days. Omeprazole continues until 30 days from initiating the treatment.

Category

2**Description**

Intervention 2 (Control): Triple therapy with omeprazole (DR. Abidi Co.) 1mg/Kg(30 days), plus amoxicillin (Farabi Co.) 25mg/Kg (10 days)and metronidazole (Tehranshimi Co.) 10mg/Kg (10 days).all drugs use twice a day.

Category

Treatment - Drugs

Recruitment centers1**Recruitment center****Name of recruitment center**

Children 's Medical Center Hospital

Full name of responsible person

Parisa Rashtian

Street address

No.62, Dr. Gharib Street, end of Keshavarz Boulevard

City

Tehran

Sponsors / Funding sources1**Sponsor****Name of organization / entity**

Vice chancellor for research, Tehran University of Medical Sciences

Full name of responsible person

Masood Yunesian

Street address

Tehran University of Medical Sciences, Ghods Street, Keshavarz Boulevard

City

Tehran

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

Yes

Title of funding source

Vice chancellor for research, Tehran 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**

Tehran University of Medical Sciences

Full name of responsible person

Masood Unesian

Position

Vice chancellor for research, Tehran University of Medical Sciences

Other areas of specialty/work**Street address**

Tehran University of Medical Sciences, Ghods Street, Keshavarz Boulevard

City

Tehran

Postal code

141556447

Phone

+98 21 8896 2510

Fax**Email**

chmc@tums.ac.ir

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Children' Medical Center

Full name of responsible person

Fatemah Farahmand

Position

Pediatric Gastroenterologist, Full Professor

Other areas of specialty/work**Street address**

Children's Medical Center, No.62, Dr. Gharib Street, end of Keshavarz Boulevard

City

Tehran

Postal code**Phone**

+98 21 61475

Fax**Email**

chmc@tums.ac.ir

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

Children's Medical Center

Full name of responsible person

Parisa Rashtian

Position

Pediatrician, Fellowship of Pediatric Gastroenterology

Other areas of specialty/work**Street address**

Children's Medical Center, No.62, Dr. Gharib Street, end of Keshavarz Boulevard

City
Tehran
Postal code
1419733151
Phone
+98 21 61475
Fax
Email
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