# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 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
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Iran (Islamic Republic of)
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**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 pomp 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/م

## 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**

Treatment - Drugs

**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 centers

**1**

**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 sources

**1**

**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

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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**

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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*