Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Jun 2026

Comparison of the effect of antibiotic with antibiotic and probiotic combination in the eradication of Helicobacter Pylori infection in children by a randomized clinical trial

Protocol summary

Summary

The aim of the study is to compare the eradication rate of Helicobacter Pylori infection in patients receiving standard triple-drug treatment with those who receive probiotics in addittion to the standard regimen in children 2-14 years old in Children Medical Center Hospital. a randomized double blind clinical trial, placebo controlled, single center Inclusion criteria: more than 2 and less than 14 years of age; Gastrointestinal symptoms; confirmation of Helicobacter pylori infection by rapid urease test or histopathology. Exclusion criteria: The use of proton pump inhibitors, H2 receptor antagonists, , bismuth compounds and antibiotics in the past 4 weeks; The history of surgery on the stomach; Sensitivity to certain types of antibiotics; G6PD enzyme deficiency; known underlying disease. sample size for each of case and control groups: 33. All Helicobacter Pylori positive patients are randomized into one of the A and B groups; amoxicillin and furazolidone are given for a week and omeprazole for 4 weeks for all of them. In addition to the standard regimen patients randomly receive either probiotics or placebo for 2 weeks .The fecal antigen test is performed to evaluate the eradication rate at least 4 weeks after discontinuation of omeprazole.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201201218793N1**
Registration date: **2012-04-09, 1391/01/21**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2012-04-09, 1391/01/21

Registrant information

Name
Ahmad Khodadad
Name of organization / entity
Tehran University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 98216692445
Email address
khodadadmd@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2012-01-21, 1390/11/01

Expected recruitment end date

2012-04-18, 1391/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of antibiotic with antibiotic and probiotic combination in the eradication of Helicobacter Pylori infection in children by a randomized clinical trial

Public title

Probiotics in the treatment of Helicobacter Pylori infection

Purpose

Treatment

Inclusion/Exclusion criteria
Inclusion criteria: more than 2 and less than 14 years of age; gastrointestinal symptoms including epigastric tenderness, abdominal pain at night, worsening of abdominal pain by eating, early satiety, abdominal pain or weight loss without a known cause, frequent vomiting and Iron deficiency anemia; confirmation of Helicobacter Pylori infection by rapid urease test or histopathology. Exclusion criteria: use of proton pump inhibitors, H2 receptor antagonists, bismuth compounds and antibiotics in the past 4 weeks; history of surgery on the stomach; sensitivity to certain types of antibiotics; G6PD enzyme deficiency(in these patients the use of furazolidone may lead to anemia); known underlying disease including renal failure, heart disease or endocrine disease.

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

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **66**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Tehran University of Medical Sciences

Street address
Headquarter for Tehran University of Medical Sciences, On the Corner of Keshavarz Blvd. and Qods Street, Keshavarz Blvd., Vali-e-Asr Square, Tehran, Iran.

City
Tehran

Postal code

Approval date
2012-01-28, 1390/11/08

Ethics committee reference number
2097

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

Primary outcomes

1

Description
eradication rate of helicobacter pylori

Timepoint
after two months of the treatment

Method of measurement
stool antigen for helicobacter pylori

Secondary outcomes

1

Description
endoscopic finding

Timepoint
at the time of endoscopy

Method of measurement
by the report of the person performing the endoscopy

2

Description
adverse effects of the drugs

Timepoint
during the course of treatment

Method of measurement
subjective /asking the patients and parents

3

Description
concordance of the result of rapid urease test and pathology report

Timepoint
after the pathology report is prepared

Method of measurement
The comparison of the result of urease test with histopathological report by the researchers

Intervention groups

1

Description
In the intervention group Amoxicillin (dose 50 mg / kg / day/divided in 2 doses) and Furazolidone (dose of 6 mg / kg / day/divided in 2 doses) for 1 week and Omeprazole

for 4 weeks (with a dose of 1 mg / kg / day/once at morning) are prescribed. Amoxicillin and Furazolidone tablets or syrup forms based on the child's age are given. In addition, patients in this group receive probiotics for 2 weeks. The probiotic is named RESTORE, the product of Protexin company that contains 7 types of probiotics including Lactobacillus Acidophilus, Lactobacillus Rhamnosus, Lactobacillus Bulgaricus, Lactobacillus Casei, Streptococcus Thermophilus, Bifidobacterium Infantis(child specific), Bifidobacterium breve. This product is given once daily after breakfast.

Category

Treatment - Drugs

2

Description

In the control group Amoxicillin (dose 50 mg / kg / day/divided in 2 doses) and Furazolidone (dose of 6 mg / kg / day/divided in 2 doses) for 1 week and Omeprazole for 4 weeks (with a dose of 1 mg / kg / day/once at morning) are prescribed. Amoxicillin and Furazolidone tablets or syrup forms based on the child's age are given. In addition to the standard regimen, in the control group, the patients receive placebo in the first 2 weeks. Placebo is a product seeming just like the probiotic and is composed of dextrose. This product is prepared by Protexin company and is prescribed once daily after breakfast similar to the RESTORE probiotic.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Children Medical Center Hospital

Full name of responsible person

Maryam Shoaran

Street address

Endoscopy ward-Children Medical Center,Qarib St, Keshavarz Blvd

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Ahmad Khodadad

Street address

Children Medical Center Hospital, Qarib St, Keshavarz Blvd

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

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

Maryam Shoaran

Position

Pediatrician-Fellowship of Pediatric Gastroenterology

Other areas of specialty/work

Street address

Endoscopy Ward, Children Medical Center Hospital,Qarib St, Keshavarz Blvd

City

Tehran

Postal code

Phone

+98 21 6692 4545

Fax

Email

maryamshoaran@yahoo.com; maryamshoaran1@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Ahmad Khodadad

Position

Pediatrician-Academic Staff- Pediatric Gastroenterologist

Other areas of specialty/work

Street address

Endoscopy Ward, Children Medical Center Hospital, Qarib St, Keshavarz Blvd

City

Tehran

Postal code

Phone

+98 21 6692 4545

Fax

Email

khodadadmd@yahoo.com;
ahmadkhodadad@gmail.com;
khodadadmd@sina.tums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Maryam Shoaran

Position

Pediatrician-Fellowship of Pediatric Gastroenterology

Other areas of specialty/work

Street address

Endoscopy Ward, Children Medical Center,Qarib St, Keshavarz Blvd

City

Tehran

Postal code

Phone

+98 21 6692 4545

Fax

Email

maryamshoaran@yahoo.com;
maryamshoaran1@gmail.com

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