

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Effect of sequential therapy on treatment of helicobacter pylori in children

Protocol summary

Summary

Objectives: To evaluate the efficacy of the sequential therapy and comparing it with another treatment regimens that was done in this center for eradication of H.pylori, in order to select a treatment regimen that is most effective with least adverse effects. **Inclusion criteria:** age < 18 years; gastrointestinal symptoms with suspected H.pylori infection; abdominal pain; nausea; vomiting; halitosis; gastrointestinal bleeding. **Patients and Methods:** In this study, 40 children with symptoms of H. Pylori that the infection was proved by endoscopy and biopsy and rapid urease test (UBT) were enrolled, **Intervention:** Sequential therapy (Lansoprazol, Amoxicillin) for 5 days and (Lansoprazol, Metronidazole and Clarithromycin) for next 5 days. **Main outcome measures:** The eradication rate of therapy was evaluated by stool antigen test 6 weeks after completion of therapy.

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Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2013-01-01, 1391/10/12

Expected recruitment end date

2015-12-29, 1394/10/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201702179101N3**

Registration date: **2017-04-23, 1396/02/03**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-04-23, 1396/02/03

Registrant information

Name

Seyed Mohsen Dehghani

Name of organization / entity

Shiraz University of Medical Sciences

Country

Scientific title

Effect of sequential therapy on treatment of helicobacter pylori in children

Public title

Effect of Sequential Therapy on Treatment of Helicobacter Pylori Infection in Children

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age < 18 years; gastrointestinal symptoms with suspected H.pylori infection; abdominal pain; nausea; vomiting; halitosis; gastrointestinal bleeding. **Exclusion criteria:** History of antibiotic consumption

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 40

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethical Committee of Shiraz University of Medical Sciences

Street address

Shiraz University of Medical Sciences, Zand St., Shiraz, Iran

City

Shiraz

Postal code**Approval date**

2010-08-20, 1389/05/29

Ethics committee reference number

IR.SUMS.MED.REC.1394.54

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**

Eradication of Helicobacter Pylori Infection

Timepoint

Six week after treatment

Method of measurement

Stool antigen

Secondary outcomes**1****Description**

Treatment side effect

Timepoint

6 weeks after treatment

Method of measurement

History and physical examination

Intervention groups**1****Description**

(Lansoprazol, Amoxicillin) for 5 days and (Lansoprazol, Metronidazole and Clarithromycin) for next 5 days.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Nemazee Teaching Hospital

Full name of responsible person

Seyed Mohsen Dehghani

Street address

Dept. of Pediatric Gastroenterology, Nemazee Hospital, Nemazee Sq., Shiraz University of Medical Sciences, Shiraz, Iran

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice Chancellor of Research Affairs of Shiraz University of Medical Sciences

Full name of responsible person

Seyed Basir Hashemi

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Shiraz University of Medical Sciences, Zand St, Shiraz, Iran

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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

Vice Chancellor of Research Affairs of Shiraz 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
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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