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.

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

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Seyed Mohsen Dehghani
Name of organization / entity
Shiraz University of Medical Sciences
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Iran (Islamic Republic of)
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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

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
Ehical Comittee 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
City
Shiraz

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
Street address
Shiraz University of Medical Sciences, Zand St, Shiraz, Iran
City
Shiraz
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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Position
Professor

Other areas of specialty/work

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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