Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison efficacy the three- drug regimen of Helicobacter Pylori eradication Amoxicillin, Omeprazole, with Clarithromycin or Azithromycin in children

Protocol summary

Summary

Objective: The comparison of the therapeutic effect of Azithromycin instead of Clarithromycin concerning the eradication of Helicobacter Pylori [H.pylori] with tolerance in children and triple therapy accompanying Omeprazole and Amoxicillin. Inclusion Criteria: Two to 15 year-old children who refer to Amirkola Hospital with gastrointestinal symptoms associated with Helicobacter Pylori [H.pylori] whose stomach's biopsy diagnosed Helicobacter Pylori. Exclusion Criteria: The use of antibiotic since 2 months earlier; children beyond 2 to 15 years of age; drug allergies to medications during the study compared; chronic liver and renal diseases. The subjects of the study: The children who refer to Children's Digestive Clinic of Amirkola Children's Hospital. The sample size: Sixty subjects were divided into two groups of 30. The study duration: Within 2014 Intervention of the study: A group of Omeperazole manufatured by Abidie Company 1mg/kg/day every 12 hours for two weeks. Amoxicillin manufactured by Farabi Company 50 mg/kg/day every 12 hours for 10 days. Clarithromycin manufactured by Chemidarou and Rouzdarou Company 15 mg/kg/day every 12 hours for 10 days. Omeprazole and Amoxicillin were given on the same condition in the other group and Azithromycin manufactured by Tehran Shimi and Kharazmy 10 mg/kg/day once a day for 6 days. Primary outcome: The evaluation of response to treatment within 4 to 6 weeks after the treatment is done and the measurement of Helicobacter Pylori Antigen in stool in monoclonol style with quick antigen of helicobactor kit from Germany and drug tolerance status and its complications.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013112115475N1**
Registration date: **2014-10-07, 1393/07/15**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-10-07, 1393/07/15

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Babol University of Medical Sciences

Expected recruitment start date

2014-04-30, 1393/02/10

Expected recruitment end date

2015-03-19, 1393/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison efficacy the three- drug regimen of

Helicobacter Pylori eradication Amoxicillin, Omeprazole, with Clarithromycin or Azithromycin in children

Public title
The Eradication of Helicobacter Pylori [H.pylori] in children
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Two to 15 year old children with gastrointestinal symptoms associated with Helicobacter Pylori that need upper Gastro Intestinal whose Gastric biopsy diganosed Helicobacter Pylori Endoscopy and have been referred to the Amirkola Children’s Hospital. Exclusion criteria: Use of antibiotics 2 months ago; children beyond ages of 2 to 15 years; drug allergies to medications used in the study; chronic liver and renal disease; taking non steroidal anti inflammatory drugs; patients who have been previously treated for Helicobacter Pylori.
Age
From **2 years** old to **15 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size:
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
Babol University of Medical Sciences
Street address
Vice- Chancellor for Research Technology Affairs, Babol University of Medical Sciences, Ganjafroz Street, Babol, Mazandaran Province, IR Iran.
City
Babol
Postal code
4717647745
Approval date
2014-04-22, 1393/02/02
Ethics committee reference number
4018.30.ژ.پ

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
The detection Status of Helicobacter Pylori antigen in stool
Timepoint
Four to 6 weeks after the treatment is over
Method of measurement
Check on the stool antigen from Helicobacter Pylori point of view in a Monoclonal Method with Helicobacter Antigen Quick kit

Secondary outcomes

1

Description
The status of drug tolerance and side effects
Timepoint
Within treatment till the end of treatment span
Method of measurement
Check on the Helicobacter Pylori stool antigen

Intervention groups

1

Description
Intervention 1: Azithromycin manufactured by Tehran Shimi Company and Khrazmi 10 mg/kg/day once a day for 6 days using with Amoxicillin manufactured by Farabi Company 50 mg/kg/day every 12 hours for 10 days and Omeprazole developed by Abidy Company 1 mg/kg/day every 12 hours for two weeks.
Category
Treatment - Drugs

2

Description
Intervention 2: Clarithromycin developed by Chemidarou and Rouzdarou Company 15 mg /kg/day every 12 hours for 10 days using with Amoxicillin and Omeprazole.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Amirkola Children’s Hospital
Full name of responsible person
Dr Mohammadreza Esmaeili
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City
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Vice- Chancellor for Research Technology Affairs
Street address
Vice- Chancellor for Research Technology Affairs, Babol University of Medical Sciences, Ganjafroz Street.
City
Babol
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Babol 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
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Hossein Shirdel
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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