

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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 Omeprazole manufactured 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 monoclonal style with quick antigen of helicobacter 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

###### Name

Hossein Shirdel

###### Name of organization / entity

Babol University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 11 3235 4951

###### Email address

shierdel.h@mubabol.ac.ir

##### 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

2014-04-22, 1393/02/02

**Ethics committee reference number**  
4018.30. ژ.پ.

## 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

## 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

**Street address**

No 19, Amirkola Children's Hospital, Amirkola.

**City**

Babol

**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****Name of organization / entity**

Amirkola Children's Hospital

**Full name of responsible person**

Hossein Shirdel

**Position**

Pediatric Assistant

**Other areas of specialty/work****Street address**

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Amirkola Children's Hospital

**Full name of responsible person**

Dr Mohammadreza Esmaeili

**Position**

Pediatric Gastroenterologist

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Amirkola Children's Hospital

**Full name of responsible person**

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**Position**

pediatric Assistant

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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*