

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jun 2026

### Comparison between therapy regimen of amoxicillin,omeperazole,metronidazole and therapy regimen of amoxicillin,omeperazole,metronidazole and kidilact for treatment of helicobacter pylori infection in children 5 to 18 years in Imam Ali clinic of Shahrekord

#### Protocol summary

##### Summary

The goal of this study is to compare the efficacy of amoxicillin, omeperazole, metronidazole with amoxicillin, omeperazole, metronidazole and Kidilact on the eradication of helicobacter pylori in children 5 to 18 years old. Inclusion criteria: patients under 18 who have undergone endoscopy because of gastrointestinal problems; Patients having gastrointestinal problems who have written consent for inclusion after receiving a full explanation of the study. Exclusion criteria: allergy to any of the drugs used; drug side effect such as vomiting or severe abdominal pain; previous H-pylori eradication therapy; recent use of probiotics, antibiotics or anti acids. The study population is selected of children 5 to 18 that are referred to Imam Ali clinic of Shahrekord due to gastrointestinal disorders. The total sample size is 132. Case group intervention in this study is standard triple therapy that includes amoxicillin 25 milligram per kilogram, two times a day ( maximum 1 gram ) ; metronidazole 15 to 20 milligram per kilogram , two times a day; omeprazole 1 milligram per kilogram twice a day . And a sachet of kidilact once a day.( each sachet contains 109 CFU probiotics) this treatment is given for two weeks. Omeperazole is given for 4 weeks. The intervention in control group is standard triple therapy without kidilact. estimated time of the study is 10 months. The primary outcome of study is to achieve a more effective therapy for eradication of helicobacter pylori that has lesser complication.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017051433965N1**

Registration date: **2017-07-05, 1396/04/14**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2017-07-05, 1396/04/14

##### Registrant information

###### Name

Niloofar Kasiri

###### Name of organization / entity

Zahedan University Of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 54 3329 5715

###### Email address

n.kasiri@zaums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Zahedan University of Medical Sciences

##### Expected recruitment start date

2017-07-23, 1396/05/01

##### Expected recruitment end date

2017-10-23, 1396/08/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Comparison between therapy regimen of amoxicillin,omeperazole,metronidazole and therapy regimen of amoxicillin,omeperazole,metronidazole and kidilact for treatment of helicobacter pylori infection in children 5 to 18 years in Imam Ali clinic of Shahrekord

## Public title

kidilact effect on stomach infection

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: patients younger than 18 years old that are referred to Imam Ali clinic of Shahrekord because of gastrointestinal problems and have under gone endoscopy and Helicobacter Pylori is approved with rapid urease test, pathology or stool antigen ; Patients having gastrointestinal problems who have written consent for inclusion after receiving a full explanation of the treatment, drugs used, duration of treatment and possible side effects Exclusion criteria: Patients who have allergy to any of the medications amoxicillin, omeprazole, metronidazole, kidilact ; Patients who experience complications such as severe or unbearable pain ,severe vomiting during study ; Patients who want to leave the study for any reason during the study; patients who previously were treated with Helicobacter pylori eradication regimen; The recent use of probiotics, antibiotics, anti-acid

## Age

From **5 years** old to **18 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **65**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Zahedan University of Medical Science

## Street address

Zahedan University of Medical Science, Doctor hesabi square, Zahedan

## City

Zahedan

## Postal code

## Approval date

2017-03-07, 1395/12/17

## Ethics committee reference number

IR.ZAUMS.REC.1395.105

## Health conditions studied

### 1

#### Description of health condition studied

Helicobacter pylori infection of stomach

#### 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

Helicobacter pylori eradication rate

#### Timepoint

2 weeks after end of treatment

#### Method of measurement

Stool antigen Test

## Secondary outcomes

### 1

#### Description

Therapy side effects rate

#### Timepoint

Day 14 of treatment, 2 weeks after completion of antibiotic therapy and 4 to 6 weeks after completion of antibiotic therapy

#### Method of measurement

Check list that is completed by parents include diarrhea, constipation, nausea, vomiting, abdominal pain, heartburn, early satiety, decreased appetite, belching, metallic taste in mouth, halitosis and hives

## Intervention groups

### 1

#### Description

Therapy regimen of amoxicillin,omeperazole,metronidazole in control group

#### Category

Treatment - Drugs

## 2

### Description

Therapy regimen of amoxicillin,omeperazole,metronidazole and kidilact in intervention group

### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Imam Ali clinic of Shahrekord

##### Full name of responsible person

Doctor Karam ali Kasiri

##### Street address

Basij square, Imam Ali clinic of Shahrekord

##### City

Shahrekord

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Zahedan University of Medical Sciences

##### Full name of responsible person

Doctor Hooshang Rafighdoost

##### Street address

Zahedan University of Medical Sciences, Zahedan

##### City

Zahedan

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Zahedan 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

Shahrekord University of Medical Sciences

##### Full name of responsible person

Doctor Karam Ali Kasiri

#### Position

Pediatric Gastroenterologist

#### Other areas of specialty/work

#### Street address

Hajar Hospital of Shahrekord, Shahrekord

#### City

Shahrekord

#### Postal code

#### Phone

+98 38 3334 3701

#### Fax

#### Email

kasiri2007@yahoo.com

#### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Zahedan University of Medical Sciences

##### Full name of responsible person

Doctor Manijeh Khalili

##### Position

Pediatric Gastroenterologist

##### Other areas of specialty/work

##### Street address

Zahedan, Doctor Hesabi square, Zahedan University of Medical Sciences

##### City

Zahedan

##### Postal code

##### Phone

+98 54 3329 5715

##### Fax

##### Email

dr\_khalil2000@yahoo.com

##### Web page address

## Person responsible for updating data

#### Contact

##### Name of organization / entity

Zahedan University of Medical Sciences

##### Full name of responsible person

Niloofer Kasiri

##### Position

medical student

##### Other areas of specialty/work

##### Street address

Alley number 7, 17 Shahrivar street, Shahrekord

##### City

Shahrekord

##### Postal code

##### Phone

+98 38 3334 3701

##### Fax

##### Email

niloofer.kasiri2000@yahoo.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*