

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 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

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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 Shahrekor

Full name of responsible person

Doctor Karam ali Kasiri

Street address

Basij square, Imam Ali clinic of Shahrekor

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

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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

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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