

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 2026

Comparative evaluation of triple therapy with high dose amoxicillin versus bismuth-based therapy in second-line therapy for eradication of helicobacter pylori infection in children

Protocol summary

Study aim

Comparative evaluation of triple therapy with high dose amoxicillin versus bismuth-based therapy in second-line therapy for eradication of helicobacter pylori infection in children

Design

In this study, patients referring to the gastroenterology clinic of Qods Hospital in Qazvin, aged 18-18 years, were studied by a project designer for one and a half years. Patients will be randomly assigned to two A / B treatment groups . Patients are not aware of group allocation. The efficacy of triple-drug therapy with high-dose amoxicillin and bismuth-based therapy in the eradication of stage II Helicobacter pylori infection in children is compared.

Settings and conduct

The aim of this study was to evaluate the efficacy of triple-drug therapy with high dose amoxicillin and bismuth-based therapy in eradicating second stage Helicobacter pylori infection in children aged 18-18 years. To be.

Participants/Inclusion and exclusion criteria

Children with Helicobacter pylori infection who are known to be resistant to the first stage of eradication. Patients who have had a positive history of antibiotic, bismuth, proton pump inhibitors, histamine receptor 2 antagonist or non-steroidal anti-inflammatory drugs during the last 4 weeks.

Intervention groups

In group A, patients were treated with a high dose of omeprazole, metronidazole, amoxicillin, and folic acid over a 14-day period. In group B patients during a 14-day period treated with omeprazole, metronidazole Amoxicillin and bismuth subcitrate.

Main outcome variables

The percentage of patients with Helicobacter pylori antigen in their stool is negative.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191022045195N1**

Registration date: **2020-01-08, 1398/10/18**

Registration timing: **registered_while_recruiting**

Last update: **2020-01-08, 1398/10/18**

Update count: **0**

Registration date

2020-01-08, 1398/10/18

Registrant information

Name

Zahra Tohidlou

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3334 4157

Email address

ztohidlou@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-11, 1398/08/20

Expected recruitment end date

2020-05-30, 1399/03/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative evaluation of triple therapy with high dose amoxicillin versus bismuth-based therapy in second-line therapy for eradication of helicobacter pylori infection in children

Public title

Comparative evaluation of triple therapy with high dose amoxicillin versus bismuth-based therapy in second-line therapy for eradication of helicobacter pylori infection in children

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Children with Helicobacter pylori infection who are known to be resistant to the first stage of eradication

Exclusion criteria:

Patients who have had a positive history of taking drugs such as antibiotics during the last 4 weeks, Bismuth, proton pump inhibitor, histamine receptor antagonist 2 or non-steroidal anti-inflammatory drug are excluded

Age

From **1 year** old to **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **50**

More than 1 sample in each individual

Number of samples in each individual: **1**

In group A, patients were treated with a high dose of omeprazole, metronidazole, amoxicillin, and folic acid over a 14-day period. In group B patients during a 14-day period treated with omeprazole, metronidazole, Amoxicillin and bismuth subcitrate.

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were randomly assigned based on a random number table (with the creation of binary blocks and then based on a random number table) after defining treatment regimens and explaining how they were administered and satisfaction of parents and children over the age of 7 years. A / B therapy will be assigned.

Blinding (investigator's opinion)

Single blinded

Blinding description

We have two therapies so we can build 6 quadruple blocks if we want to randomly block people. As follows: AABB, BBAA, ABAB, BABA, ABBA, BAAB We give each of these blocks a number from 1 to 6 and then randomly select these numbers from 1 to 6, for example if 3 randomly selected ABAB combinations are given, namely the first with treatment A, the second with treatment B, Nephersum is treated with treatment A and the fourth with treatment B. First we must first identify the blocks and number them each block inside an envelope that

cannot be seen inside and then using a random number table based on the accident number A number that is the number one envelope is selected. Put the blocks in the envelope by someone who is not involved in the research.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Qazvin University of Medical Sciences

Street address

Qazvin - Qods Children's Hospital

City

Qazvin

Province

Qazvin

Postal code

3415914595

Approval date

2019-11-06, 1398/08/15

Ethics committee reference number

IR.QUMS.REC.1398.180

Health conditions studied

1

Description of health condition studied

H.pylori Gastritis

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 percentage of patients with Helicobacter pylori antigen in the stool sample is negative

Timepoint

Helicobacter pylori antigen assay is performed within 4 to 6 weeks after completion of treatment.

Method of measurement

Helicobacter pylori antigen in stool sample by ELISA

Secondary outcomes

1

Description

Percentage of people with side effects while taking the drug

Timepoint

From the beginning of the drug to the end of the study

Method of measurement

Self-expression of the patient, parents or carers

2

Description

Percentage of patients who were fully compliant with medication

Timepoint

Up to 4 weeks after starting the drug

Method of measurement

Self-expression of the patient, parents or carers

Intervention groups

1

Description

Intervention group 1: Patients will be treated with omeprazole, metronidazole, high-dose amoxicillin, and folic acid over a 14-day period. It should be noted that omeprazole is administered as a 1mg / kg capsule in two doses in the morning before breakfast and dinner for 28 days. In a dose of 75mg / kg suspension or capsule, it is administered in two divided doses for 14 days. Folic acid is administered to patients in this group at a dose of 1 mg once daily. The cause of placement of this fourth drug as placebo in this drug group is to prevent any possible bias in the placement of patients in any of the three or four drug groups. .Pharmaceutical Companies Name: Amoxicillin Suspension or Capsule (Manufactured by Farabi Company), Folic Acid as a Tablet (Manufactured by Enamel), Omoperazole as Capsule (Manufactured by Obidi Co.), Metronidazole as Syrup or Tablet (Manufactured by Alborz Drug Company) Bismuth Sub Citrate in tablet form (manufactured by Aria).

Category

Treatment - Drugs

2

Description

Intervention group: Intervention group 2: Patients will be treated with omeprazole, metronidazole, amoxicillin and bismuth subcitrate over a 14-day period. It should be noted that omeprazole is a 1mg / kg capsule in two doses before breakfast and dinner It is prescribed overnight for 28 days. Metronidazole 20 mg / kg syrup or tablet in two divided doses and Amoxicillin 50 mg / kg suspension or capsule in two divided doses and Substratum bismuth drug in 8 mg / kg doses in two divided doses Prescribed. Patients in each group will be monitored appropriately for possible drug use and any

possible side effects of the medications used. Patients in each group will be without medication for at least 4 weeks after completion of treatment. Helicobacter pylori antigen screening is performed within 4 to 6 weeks after completion of treatment. If the test results are negative, the effect of helicobacter pylori eradication therapy is considered successful in the second phase of treatment. In the next step, the study data will be analyzed after collecting and completing the relevant checklist and then the results will be compared in each group. It should be noted that in any case of a candidate for Helicobacter pylori eradication treatment, he or she will need treatment, whether it is part of a research project or not.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Qods Children's Hospital

Full name of responsible person

Zahra Tohidlou

Street address

Qazvin Shahid Beheshti Boulevard, beginning of East Palestine, Qods Square, Qods Medical Center

City

Qazvin

Province

Qazvin

Postal code

3415914595

Phone

+98 28 3334 8070

Fax

+98 28 3344 0880

Email

hosghods@qums.ac.ir

Web page address

<http://qums.ac.ir>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Mohammad Mahdi Emamjome

Street address

Qazvin - Shahid Bahonar Boulevard - Qazvin University of Medical Sciences

City

Qazvin

Province

Qazvin

Postal code

4595134159

Phone

+98 28 3333 4807

Fax**Email**

Cgd_rc@yahoo.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Qazvin University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Qazvin University of Medical Sciences

Full name of responsible person

Rita Bagherian

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

Street address

Shahid Beheshti Boulevard, east of Palestine, Quds Square

City

Qazvin

Province

Qazvin

Postal code

3415914595

Phone

+98 28 3333 4807

Email

r.bagherian@qums.ac.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Qazvin University of Medical Sciences

Full name of responsible person

Rita Bagherian

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

Street address

Shahid Beheshti Boulevard, east of Palestine, Quds Square, Quds Hospital

City

Qazvin

Province

Qazvin

Postal code

3415914595

Phone

+98 28 3333 4807

Email

r.bagherian@qums.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Qazvin University of Medical Sciences

Full name of responsible person

Zahra Tohidlou

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

Street address

Shahid Beheshti Boulevard, east of Palestine, Quds Square, Quds Hospital

City

Qazvin

Province

Qazvin

Postal code

3415914595

Phone

+98 28 3333 4807

Email

ztohidlou@gmail.com

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available