Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

Comparison of Helicobacter pylori eradication treatment in children with chronic gastritis with non-eradication treatment of Helicobacter pylori in patients with chronic gastritis

Protocol summary

Study aim
Determining the comparative effect of Helicobacter pylori eradication treatment in children with chronic gastritis with no Helicobacter pylori eradication treatment in the recovery of patients with chronic gastritis.

Design
A single-blind, randomized,phase 2 clinical trial in 80 patients.The method of randomization will be a simple randomization, so that2 cards with the letters A and B are placed in front of the patient's parents and they choose one.Each letter belongs to one of2 groups.

Settings and conduct
In the present clinical trial, which is in the form of a blind, so that the patient will not know which group he belongs to. A total of 80 children aged 5-15 years old who referred to Hajer Shahrekord Hospital due to chronic abdominal pain and underwent endoscopy and were suffering from chronic gastritis. And of them, gastric biopsy was performed, and as a result of the biopsy, chronic inflammation of the stomach was reported, and Helicobacter pylori infection was reported in the histology, and at the same time, the patient's rapid urease test was positive, and they are included in the study.

Participants/Inclusion and exclusion criteria
Exclusion criteria: Consent of parents to participate in the study. Exclusion criteria: evidence of ulcers or any other pathology other than chronic gastritis in the stomach, esophagus or duodenum, functional abdominal pain, Malt's lymphoma, atrophic gastritis or hemi-sideroblastic anemia, suffering from ITP or hiatal hernia or a history of stomach cancer in first degree relatives.

Intervention groups
In group A, 40 children (helicobacter pylori and gastritis treatment will become chronic) . Group B, 40 children will receive only proton pump inhibitor (Someprazole) for 2 months

Main outcome variables
Frequency and severity of heartburn, reflux (GERD), localized poor abdominal pain, diffuse abdominal pain, epigastric abdominal pain, dyspepsia, vomiting.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230612058464N1**
Registration date: **2023-07-24, 1402/05/02**
Registration timing: **retrospective**

Last update: **2023-07-24, 1402/05/02**
Update count: **0**

Registration date
2023-07-24, 1402/05/02

Registrant information

Name
Ali agheel

Name of organization / entity
Olom pezeshki share kord

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Iran (Islamic Republic of)

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Email address
dr.agheel@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-06-14, 1402/03/24

Expected recruitment end date

2023-07-14, 1402/04/23

Actual recruitment start date

2023-06-14, 1402/03/24

Actual recruitment end date

2023-07-14, 1402/04/23

Trial completion date

2023-07-14, 1402/04/23

Scientific title

Comparison of Helicobacter pylori eradication treatment in children with chronic gastritis with non-eradication treatment of Helicobacter pylori in patients with chronic gastritis

Public title

Comparison of Helicobacter pylori eradication treatment in children with chronic gastritis with non-eradication treatment of Helicobacter pylori in patients with chronic gastritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Parental consent to participate in the study Patients with no history of stomach cancer in children with Helicobacter pylori positive chronic gastritis, which is positive at the same time as the patient's RUT test, and the patient's history and clinical examination with the patient's endoscopic view and pathology report according to first degree relatives

Exclusion criteria:

Lack of parental consent to participate in the study Evidence of ulcers or any other pathology other than chronic gastritis in the stomach, esophagus and duodenum. Functional abdominal pain. Mallet's lymphoma. Hemi-sideroplastic anemia ITP Hiatal hernia Patients with history of stomach cancer in first-degree relatives

Age

From **5 years** old to **15 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **80**

Actual sample size reached: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

The method of randomization will be a simple randomization, so that 2 cards with the letters A and B are placed in front of the patient's parents and they choose one. Each letter belongs to one of 2 groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

According to the Helicobacter pylori treatment guidelines, both treatments are approved, and at the beginning of the study, the method of treatment will be explained to the parents of the participants, and only the parents will know about the type of treatment and the child will not know about the type of treatment, so the study is a single-blind study.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahre-kord University of Medical Sciences

Street address

8, Fourth Ave., Shariati Blvd. Shahrekord city

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Province

Chahar-Mahal-va-Bakhtiari

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8815844345

Approval date

2023-06-12, 1402/03/22

Ethics committee reference number

IR.SKUMS.MED.REC.1402.015

Health conditions studied

1

Description of health condition studied

Helicobacter positive chronic gastritis

ICD-10 code

R10.84

ICD-10 code description

Generalized abdominal pain

Primary outcomes

1

Description

Regurgitation frequency

Timepoint

before the study and after 2 months and after 4 months of treatment

Method of measurement

number

2

Description

Frequent heartburn

Timepoint

before the study and after 2 months and after 4 months of treatment

Method of measurement

number

3

Description

Vomiting frequency

Timepoint

before the study and after 2 months and after 4 months of treatment

Method of measurement

number

4

Description

Abdominal pain frequency localized poorly

Timepoint

before the study and after 2 months and after 4 months of treatment

Method of measurement

number

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: A group of 20 children in such a way that the first 10 days of sequential therapy with S-Omeprazole 2 mg/kg/day in two divided doses and simultaneous Helicobacter pylori antibiotic treatment, first a 5-day course of amoxicillin 50 mg/kg/day in two divided doses And then on the second 5 days, they will receive clarithromycin 15 mg/kg/day in two divided doses and metronidazole 20 mg/kg/day in two divided doses, and then they will receive omeprazole 1 mg/kg/day in a single daily dose for 50 days. Helicobacter pylori antigen in stool is checked 4-8 weeks after the eradication treatment to ensure the treatment.

Category

Treatment - Drugs

2

Description

Intervention group: Group B, 20 children only proton pump inhibitor

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Ali Clinic

Full name of responsible person

Dr. Hassan Talakesh

Street address

Shahrekord, Shariati Blvd., Imam Ali (A.S.) Specialized Clinic

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Dr. Elham Raiesi

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahre-kord 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
Shahre-kord University of Medical Sciences

Full name of responsible person
Dr. Hassan Talakesh

Position
Assistant Professor

Latest degree
Subspecialist

Other areas of specialty/work
Pediatrics

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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
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

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

Title and more details about the data/document
There is no further information

When the data will become available and for how long
The access period starts 6 months after the results are published

To whom data/document is available
It will be available only to researchers working in academic and scientific institutions

Under which criteria data/document could be used
For research purposes

From where data/document is obtainable
Refer to the scientific and experimental officer

What processes are involved for a request to access data/document
They should refer to the study center of Shahrekord University of Medical Sciences

Comments