

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 2026

Comparing the effects of Lactobacillus Reuteri and Standard treatment in treatment of infected children with Helicobacter pylori in Imam Ali Hospital in July 2012 to November 2013.

Protocol summary

Summary

The aim of this study is evaluating the effects of Lactobacillus Reuteri in treatment of infected children with Helicobacter Pylori in Imam Ali Hospital Zahedan in July 2012 and November 2013. Primary outcomes include symptoms (abdominal pain, nausea, vomiting, diarrhea, constipation, heart burn, weight loss) that recorded in questionnaire; eradication; kind of treatment (1- Amoxicillin 50mg/kg/day, Omeprazole 1mg/kg/day, Clarithromycin 15mg/kg/day. 2- standard treatment and Lactobacillus Reuteri 1tab/12h). The study is clinical Trial, double blind, accidental. Inclusion criteria: 5-14 years old children; Chronic abdominal pain; vomiting; positive Helicobacter pylori infection in Endoscopy that target sample size were 50, Exclusion criteria: Patients with Antibiotic administration; and Proton Pump Inhibitors or Probiotics in recent two weeks; Gastric surgery history; Neurologic disease; Life Threatening disorders. Patients were distributed in two groups. 25 patients received Standard treatment three drugs for 14 days. and another group received Lactobacillus Reuteri and three drugs Standard treatment for the same period, that have treated for 14 days. and after 4-6 weeks performed UBT was performed in order to investigate eradication of Helicobacter pylori infection.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013071814048N1**

Registration date: **2013-09-20, 1392/06/29**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-09-20, 1392/06/29

Registrant information

Name

Elham Shafiqi shahri

Name of organization / entity

Zahedan University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 54 1242 2016

Email address

eshahri@yahoo.com

Recruitment status

Recruitment complete

Funding source

Zahedan University Of Medical Sciences

Expected recruitment start date

2012-06-13, 1391/03/24

Expected recruitment end date

2013-11-22, 1392/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effects of Lactobacillus Reuteri and Standard treatment in treatment of infected children with Helicobacter pylori in Imam Ali Hospital in July 2012 to November 2013.

Public title

Probiotic in treatment of Helicobacter pylori infection

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:5-14 years old children; Chronic abdominal pain ; vomiting ;positive Helicobacterpylori infection in Endoscopy . Exclusion criteria:Patients with Antibiotic adminstration;and Proton Pump Inhibitors or Probiotics in recent two weeks ;Gastric surgery history; Neurologic disease ; Life Threatening disorders.

Age

From **5 years** old to **14 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **50**

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 Sciences

Street address

Sistan and Baluchestan,Iran

City

Zahedan

Postal code

9816743463

Approval date

2012-06-12, 1391/03/23

Ethics committee reference number

91-560

Health conditions studied

1

Description of health condition studied

Helicobacterpylori 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

Vomiting

Timepoint

First and End of treatment

Method of measurement

Physical Exam and questionear

2

Description

Constipation

Timepoint

First and End of treatment

Method of measurement

Physical Exam and questionear

3

Description

Diarrhea

Timepoint

First and End of treatment

Method of measurement

Physical Exam and questionear

4

Description

Nausing

Timepoint

First and End of treatment

Method of measurement

Physical Exam and questionear

5

Description

Abdominal pain

Timepoint

First and End of treatment

Method of measurement

Physical Exam and questionear

6

Description

Heart burn

Timepoint

First and End of treatment

Method of measurement

Physical Exam and questionear

7

Description

Weight loss

Timepoint

First and End of treatment

Method of measurement

Physical Exam and questionear

Secondary outcomes

1

Description

Anemia

Timepoint

First and End Of Treatment

Method of measurement

CBC

Intervention groups

1

Description

drugs in group that received standard treatment includes Amoxicillin50mg/kg/day,Omeprazole1mg/kg/day,Clarythromycin15mg/kg/day for 14 days.

Category

Treatment - Drugs

2

Description

drugs in group that received standard treatment and Lactobacillus Reuterri includes Amoxicillin50mg/kg/day,Omeprazole1mg/kg/day,Clarythromycin15mg/kg/day, Lactobacillus Reuterri 1tab/12h for 14 days .

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Endoscopy Of Emam Ali Hospital

Full name of responsible person

Elham Shafighi Shahri

Street address

Emam Ali Hospital,Zahedan

City

Zahedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-Chancellor for research

Full name of responsible person

Dr Hamidreza Mahmoodzade Sagheb

Street address

Zahedanl University Of Medical Sciences

City

Zahedan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice-Chancellor for research

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

Zahedan University Of Medical Sciences

Full name of responsible person

Elham Shafighi Shahri

Position

Pediatric Resident

Other areas of specialty/work

Street address

Daneshgah Ave.1,Zahedan

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Zahedan University Of Medical Sciences

Full name of responsible person

Elham Shafighi Shahri

Position

Pediatric Resident.

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Elham shafighi shahri

Position

Pediatric Resident

Other areas of specialty/work

Street address

Emam Ali Hospital, Zahedan

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Zahedan

Postal code

9816867393

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