Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparing the effects of Lactobacillus Reuteri and Standard treatment in treatment of infected children with Helicobacter pylori in Imam Ali Hospital in july2012 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 obetween utcomes include symptoms(abdominal pain,nausing,vomiting,diarrhea,constipation,heart burn,weight loss)that recorded in questionaier ;eradication;kind of treatment(1-Amoxicillin50mg/kg/day,Omeprazole1mg/kg/day,Clarythromycin15mg/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 Helicobacterpylori infection in Endoscopy that target sample size were 50 , Exclusion criteria:Patients with Antibiotic adminstration;and Proton Pomp Inhibitors or Probiotics in recent two weeks ;Gastric surgery history; Nurologic 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 Rreuteri and three drugs Standard treatment for the same period, that have treated for 14days.and after 4-6 weeks performed UBT was performed in order to investigate eradication of Helicobacterpylori 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 Shafighi 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 july2012 to November 2013.

Public title

Probiotic in treatment of Helicobacterpylory 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 Pomp Inhibitors or Probiotics in recent two weeks ;Gastric surgery history; Nurologic 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 questioniear

2

Description

Constipation

Timepoint

First and End of treatment

Method of measurement

Physical Exam and questioniear

3

Description

Diarrhea

Timepoint

First and End of treatment

Method of measurement

Physical Exam and questioniear

4

Description

Nausing

Timepoint

First and End of treatment

Method of measurement

Physical Exam and questioniear

5

Description

Abdominal pain

Timepoint

First and End of treatment

Method of measurement

Physical Exam and questioniear

6

Description

Heart burn

Timepoint

First and End of treatment

Method of measurement

Physical Exam and questioniear

7

Description

Weight loss

Timepoint
First and End of treatment
Method of measurement
Physical Exam and questioniear

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
City
Zahedan
Postal code
9816867393
Phone
+98 54 1242 2016
Fax
Email
Eshahri@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
Elham Shafighi Shahri
Position
Pediatric Resident.
Other areas of specialty/work
Street address
Daneshgah Ave.1,Zahedan
City
Zahedan
Postal code

9816867393
Phone
+98 54 1242 2016
Fax
Email
Eshahri@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
Elham shafighi shahri
Position
Pediatric Resident
Other areas of specialty/work
Street address
Emam Ali Hospital, Zahedan
City
Zahedan
Postal code
9816867393
Phone
+98 54 1242 2016
Fax
Email
Eshahri@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