Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Lactobacillus Reuteri for treatment of children with Chronic Functional abdominal pain

Protocol summary

Summary

This study was a randomized double-blind placebo-controlled trial. Children aged 4 to 16 years with chronic functional abdominal pain (based on Rome III criteria) that referred to Mousavi Hospital in Zanjan, were enrolled in the study. The main inclusion criteria include: the children with functional abdominal pain (FAP) according to Rome III diagnostic criteria and the main exclusion criteria include: the children with organic abdominal pain. In this study, 80 patients were enrolled, which were randomly divided in two groups (case and control groups). The first group (case group) was given probiotic from Lactobacillus family and Reuteri strain (BioGaia® brand manufactured by Sweden Health Care company) with dose 5 drops per day orally equivalent of 108 CFU (Colony-Forming Units) for 4 weeks. The second group (control group) received placebo for the same period. Patients were followed up during and 4 weeks after cessation of treatment. On follow up period frequency and severity of pain, other symptoms and drug side effects were carefully recorded. The purpose of the study was to evaluate the effect of Lactobacillus Reuteri in treatment of children with functional abdominal pain.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014083018971N1**
Registration date: **2014-09-22, 1393/06/31**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2014-09-22, 1393/06/31

Registrant information

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Kambiz Eftekhari
Name of organization / entity
Tehran University of Medical Science
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Recruitment status

Recruitment complete

Funding source

All costs of this study have been funded by the research department of Zanjan University of Medical Sciences.

Expected recruitment start date

2014-09-23, 1393/07/01

Expected recruitment end date

2015-04-20, 1394/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Lactobacillus Reuteri for treatment of children with Chronic Functional abdominal pain

Public title

Lactobacillus Reuteri for treatment of children with abdominal pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria include: All children aged 4 to 16 years with functional abdominal pain (FAP) according to Rome III diagnostic criteria Exclusion criteria include: Have an

abdominal pain with known organic cause; history of abdominal and gastrointestinal surgery; FTT or weight loss more than 5% of body weight; any abnormal paraclinical evaluations and history of drug use in the past 3 months (including antidepressants or laxatives).

Age
From **4 years** old to **16 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Zanjan University of Medical Science

Street address
Zanjan

City
Zanjan

Postal code
4513956183

Approval date
2014-02-08, 1392/11/19

Ethics committee reference number
ZUMS.REC.1392.192

Health conditions studied

1

Description of health condition studied
Abdominal Pain

ICD-10 code
R10.4

ICD-10 code description
Other and unspecified abdominal pain

Primary outcomes

1

Description
frequency of abdominal pain

Timepoint
Baseline, one month after starting treatment and one month after discontinuing the drugs

Method of measurement
numbers of pain episode per month recorded.

2

Description
intensityof abdominal pain

Timepoint
Baseline, one month after starting treatment and one month after discontinuation of the treatment

Method of measurement
Pain intensity was assessed according to the Wong-Baker faces scale systems.

Secondary outcomes

1

Description
Assoiated Sign

Timepoint
Baseline, one month after starting treatment and one month after discontinuing the drugs

Method of measurement
Based on history and clinical examination

2

Description
Side Effects and complication

Timepoint
Baseline, one month after starting treatment and one month after discontinuing the drugs

Method of measurement
Based on history and clinical examination

Intervention groups

1

Description
The first group (case group) was given probiotic from Lactobacillus family and Reuteri strain (BioGaia® brand manufactured by Sweden Health Care company) with dose 5 drops per day orally equivalent of 108 CFU (Colony-Forming Units) for 4 weeks.

Category
Treatment - Drugs

2

Description
The second group (control group) was given placebo with

dose 5 drops per day orally for 4 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Mousavi Hospital

Full name of responsible person

Kambiz Eftekhari

Street address

Pediatric Gastroentrology clinic, Mousavi Hospital, Ghavazangh Street, Zanjan

City

Zanjan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Science

Full name of responsible person

research department of Zanjan University, Dr Aliraza Bighlari

Street address

Zanjan University of Medical Science

City

Zanjan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Zanjan University of Medical Science

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

Zanjan University of medical Science

Full name of responsible person

Kambiz Eftekhari

Position

Assistan Professor

Other areas of specialty/work

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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