

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of probiotics effect on non-organic chronic Abdominal pain in children

Protocol summary

Summary

Nonfunctional chronic abdominal pain is common disorder in child. This is a benign disease, But this is a cause of Anxiety. different mechanism is expressed. Change in bacterial environment in GI tract can lead nonfunctional abdominal pain in child. Probiotics can reduce bacterial overgrowth and reduce Mucosal Inflammation. Several studies showed effect of probiotics in nonfunctional abdominal pain in children. Aim of our study is probiotic effects on nonfunctional abdominal pain in children. Studied 52 children in a randomized, double blind and controlled study that will be selected from the outpatients of Doctor Sheikh Children's Hospital Medical Center. All children are evaluated by a pediatric gastroenterologists and diagnosed chronic abdominal pain in children. Reject organic diseases causing abdominal pain for them. All children from 4 to 18 years with gastrointestinal functional disorder consistent with ROME III criteria are entered the test. Children under the age of 4 or over 18, whom are received the drug for the treatment of chronic pain (such as drug treatment, such as herbal medicines or probiotics), or receiving drugs that are known as cause abdominal pain, are excluded from the study. By randomization is determined that which patients receive probiotics or placebo. Probiotic and placebo include at least Concentration 10^8 bacill or placebo will be provided. Placebo and probiotic in shape, size, color and taste will be similar. The probiotic and placebo will be administered 2 times a day for a period of 4 weeks.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201205219825N1**

Registration date: **2012-07-05, 1391/04/15**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-07-05, 1391/04/15

Registrant information

Name

Elham Sharbaf Eidgahi

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 1854 4643

Email address

sharbaf901@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashhad university of medical sciences

Expected recruitment start date

2012-02-29, 1390/12/10

Expected recruitment end date

2012-10-21, 1391/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of probiotics effect on non-organic chronic
Abdominal pain in children

Public title

Evaluation of probiotics effect on non-organic chronic
Abdominal pain in children

Purpose

Treatment

Inclusion/Exclusion criteria

All children from 4 to 18 years with gastrointestinal functional disorder consistent with ROME III criteria are entered the test. Children under the age of 4 or over 18, whom are received the drug for the treatment of chronic pain (such as drug treatment, such as herbal medicines or probiotics), or receiving drugs that are known as cause abdominal pain, are excluded from the study.

Age

From **4 years** old to **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **52**

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

Qureshi Building

Street address

Daneshgah Avenue

City

Mashhad

Postal code

Approval date

2012-02-18, 1390/11/29

Ethics committee reference number

89840

Health conditions studied

1

Description of health condition studied

Non-organic chronic abdominal pain in children

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Abdominal pain improvement

Timepoint

Every week to 4 weeks

Method of measurement

By patients and parents - Questionnaire forms

Secondary outcomes

1

Description

Daily activity improvement

Timepoint

Every week to 4 weeks

Method of measurement

By patients and parents - Questionnaire forms

2

Description

Change of defecation

Timepoint

Every week to 4 weeks

Method of measurement

By patients and parents - Questionnaire forms

3

Description

Change in appetite

Timepoint

Every week to 4 weeks

Method of measurement

By patients and parents - Questionnaire forms

Intervention groups

1

Description

probiotic pills - for 4weeks- 1 tablet daily - Concentration 10^7 to 10^9 bacill

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Sheikh Hospital

Full name of responsible person

Street address

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad university of medical sciences

Full name of responsible person

Dr Mohammad Ramezani

Street address

Daneshgah Avenue, Qureshi Building

City

Mashhad

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad university of medical sciences

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

Mashhad University of Medical Sciences

Full name of responsible person

Seyed Vahid Ghasemi

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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