

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparison between the efficacy of saccharomyces boulardii and placebo on treatment of pediatric functional abdominal pain

Protocol summary

Study aim

Specific goals 1. Determining the Effectiveness of Saccharomyces Bollardi in the Treatment of Pediatric Abdominal Functional Pain by Age 2- Determining the Effectiveness of Saccharomyces Bollardi in the Treatment of Pediatric Functional Abdominal Pain by Sex 3. Comparison of the efficacy of Saccharomyces Boulardi and placebo in the treatment of pediatric abdominal functional pain according to duration of treatment Practical purposes: Providing effective probiotic treatment for pediatric abdominal functional pain

Design

This study is a clinical trial on the statistical population of 104 children with functional abdominal pain between 2 and 4 years old based on Roman Criteria 3 referring to Pediatric Gastroenterology Clinic. In this study, after obtaining informed consent from enrolled patients And begin treatment with placebo or Saccharomyces Bullardi (two capsules daily containing 250 mg of Saccharomyces Bullardi). Patients receive placebo or Saccharomyces Bullardi for three weeks, during which time they complete the OUCHER questionnaire on pain intensity daily. The amount of pain felt per day and its severity are also recorded.

Settings and conduct

Children referred to the Pediatric Gastroenterology Clinic where parents and physicians are blinded to drug or placebo treatment.

Participants/Inclusion and exclusion criteria

Children with 1-5 years of age with functional abdominal pain are treated on the basis of Roman Criteria 3 referring to the Pediatric Gastrointestinal Clinic. All of these criteria must be present for at least three months and symptoms begin at least six months before diagnosis.

Intervention groups

Intervention group: Children treated with Saccharomyces Bullardi (two capsules daily containing 250 mg) Control group: children treated with placebo

Main outcome variables

Pain severity based on OUCHER questionnaire

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180822040850N1**

Registration date: **2019-11-23, 1398/09/02**

Registration timing: **retrospective**

Last update: **2019-11-23, 1398/09/02**

Update count: **0**

Registration date

2019-11-23, 1398/09/02

Registrant information

Name

Ali Dehdashtyzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3331 6243

Email address

adehdashtyzade@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-27, 1397/06/05

Expected recruitment end date

2018-10-14, 1397/07/22

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between the efficacy of saccharomyces boulardii and placebo on treatment of pediatric functional abdominal pain

Public title

Effect of saccharomyces boulardii in treatment of pediatric functional abdominal pain

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Children from 5 to 15 years old Have some 3 criteria for functional abdominal pain Participants and parents have informed consent Paraclinical is normal

Exclusion criteria:

Children who have visceral abdominal pain Children have abnormal laboratory tests findings Children have abnormal abdominal/pelvic sonography findings Parents of children have not completed the informed consent form

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **104**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, randomization of people was done by a statistical software to two blocks of 52 people. Allocation concealment is done by the central service with the code.

Blinding (investigator's opinion)

Double blinded

Blinding description

This is a double-blind study in which participants, clinical caregivers and researchers are blind about groups. Encoded participants are assigned by the Central Service. After completion of the study they will be identified, when the code is opened and assigned to the control or case groups.

Placebo

Used

Assignment

Parallel

Other design features**Secondary IDs**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Ilam University of Medical Sciences

Street address

Azadi Blv, Keshvari Sq, Ilam

City

Ilam

Province

Ilam

Postal code

7931801147

Approval date

2018-01-09, 1396/10/19

Ethics committee reference number

ir.medilam.rec.1396.110

Health conditions studied**1****Description of health condition studied**

Functional Abdominal Pain

ICD-10 code

ICD-10-CM

ICD-10 code description

Functional intestinal disorder, unspecified

Primary outcomes**1****Description**

Pain Severity

Timepoint

3 weeks after beginning of study and intervention

Method of measurement

OUCHER questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Administration of Saccharomyces Bullardi (two capsules daily containing 250 mg)

Category

Treatment - Drugs

2**Description**

Control group: treatment with Placebo

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Behesti Hospital

Full name of responsible person

Ali Dehdashtizadeh

Street address

Shahid Beheshti Hospital Complex, Qotb Ravandi Blvd,
Kashan, Iran.

City

kashan

Province

Isfahan

Postal code

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Phone

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Email

beheshtihospital@kaums.ac.ir

Web page address

<http://beheshti.kaums.ac.ir/Default.aspx?PageID=200>

2

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Ali Dehdashtizadeh

Street address

Imam Khomeini Hospital, Ayatollah Heydari St.
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6931975397

Phone

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emamkhomeinihospital@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ilam University of Medical Sciences

Full name of responsible person

Gholamreza Kalvandi

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Ilam university of medical sciences, Azadi
Blvd, Keshvari Sq, Ilam, Iran.

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Phone

+98 84 3333 4060

Email

info@medilam.ac.ir

Web page address

<http://www.medilam.ac.ir/>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ilam 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

Ilam University of Medical Sciences

Full name of responsible person

Ali Dehdashtizadeh

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries

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Full name of responsible person

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Undecided - It is not yet known if there will be 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

Finally, some of the data on study results and outcomes are generally published in the form of reports and articles.

When the data will become available and for how long

Once the study is completed and the final report is published, with no time limit.

To whom data/document is available

Researchers at academic and scientific institutes and the pharmaceutical industry

Under which criteria data/document could be used

Certain conditions are not considered

From where data/document is obtainable

Correspondence with the author or receipt of the article

What processes are involved for a request to access data/document

Upon completion of the study and writing of the report, it is possible to receive a printed article or correspondence with the project responsible by email.

Comments