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 rome 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 abnormal abdominopelvic 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
٦٩٣١٨٥١١٤٧

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.
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Phone
+98 31 5554 0026
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
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Imam Khomeini Hospital,Ayatollah Heydari St. Ilam,Iran.
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Sponsors / Funding sources

1

Sponsor
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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
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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 artice

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