

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jun 2026

Evaluation of the effects of lyophilized *Saccharomyces Boulardii* capsules on quality of life and clinical outcomes in children with inflammatory bowel disease (IBD)

Protocol summary

Study aim

Evaluation of the effects of *Saccharomyces Boulardii* on pain and quality of life in children with Inflammatory Bowel Disease (IBD)

Design

Randomized triple blind placebo-controlled clinical trial

Settings and conduct

In this study, 60 children with Inflammatory Bowel Disease hospitalized in Mofid children hospital will enroll in the study after getting informed consent from parents. The patients will be divided into two groups of intervention and control, and a drug package with a unique code will be delivered to them. The patient, the caregiver and the investigator will be blind to the package content.

Participants/Inclusion and exclusion criteria

inclusion criteria: children who aged between 1 to 16 children with IBD exclusion criteria: primary or secondary immunodeficiency

Intervention groups

one group received 2 capsules for two months that each capsule is consist of 250 milligrams *Saccharomyces Boulardii* The other group received 2 placebo capsule for two months

Main outcome variables

Pain; quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120415009475N5**

Registration date: **2018-10-10, 1397/07/18**

Registration timing: **retrospective**

Last update: **2018-10-10, 1397/07/18**

Update count: **0**

Registration date

2018-10-10, 1397/07/18

Registrant information

Name

Bahador Mirrahimi

Name of organization / entity

Shahid Beheshti University of Medical Sciences,
Faculty of Pharmacy

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-06, 1396/12/15

Expected recruitment end date

2018-09-23, 1397/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effects of lyophilized *Saccharomyces Boulardii* capsules on quality of life and clinical outcomes in children with inflammatory bowel disease (IBD)

Public title

Effects of *Saccharomyces Boulardii* capsules in pediatric Inflammatory bowel disease

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Children the age of 1-16 Children with IBD

Exclusion criteria:

primary and secondary immunodeficiency allergy to drug

Age

From **1 year** old to **16 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

the randomization has been performed using the permuted block randomization table.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The drug and placebo will be in coded same packages; a designated person will provide the codes from permuted block randomization via phone. The same person will group the data at the end of the trial, and the expert will perform statistical analysis and after results, the pocket that is with the placebo provider would be opened, and the data will be decrypted. The data regarding harm and benefits of treatment will be provided to the patient and caregiver.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Sharyati Ave., Mofid hospital

City

Tehran

Province

Tehran

Postal code

1546815514

Approval date

2017-12-30, 1396/10/09

Ethics committee reference number

IR.SBMU.PHNM.1396.888

Health conditions studied

1

Description of health condition studied

Inflammatory bowel disease

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain

Timepoint

In this study we checked the effects of Saccharomyces Boulardii capsules in the beginning of the study and two months later

Method of measurement

by interview and completing Visual Analogue Scale by patients

2

Description

Quality of life

Timepoint

In this study we checked the effects of Saccharomyces Boulardii capsules in the beginning of the study and two months later

Method of measurement

By interview and completing IMPACT III questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The patients receive two capsules for two months that each capsule contain 250 milligram Saccharomyces Boulardii

Category

Treatment - Drugs

2

Description

Control group: this group receive two placebo capsule for two months.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Mofid hospital

Full name of responsible person

Dr Pejman Rohani

Street address

Mofid Children's Hospital, Mirdamad Junction, Shariaty Ave.

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arminéh_7073@yahoo.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Seyed Ali Ziaee

Street address

3rd Floor, Faculty of medicine, Arabi Ave, Daneshjoo Blvd, Velenjak.

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Bahador Mirrahimi

Position

Asistant Profesor, Pharmacotherapy

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

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Position

Asistant Profesor, Pharmacotherapy.

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Armineh Barotkob

Position

student

Latest degree

Medical doctor

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The main outcome including questionnaire score will be available.

When the data will become available and for how long

Six months after publishing data.

To whom data/document is available

The data will be available per request for people working in academic institutions.

Under which criteria data/document could be used

the data will available for using in systematic review and meta-analysis.

From where data/document is obtainable

the data will be available by contacting email;
mirrahimi@sbmu.ac.ir.

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

The request with the systematic review protocol will be reviewed and answered in two weeks.

Comments