Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Jun 2026

A double-blind randomized clinical trial for the effectiveness of rectal enema containing a probiotic strain of Bifidobacterium longum in children with distal ulcerative colitis

Protocol summary

Study aim
The effect of rectal enema containing a probiotic strain, Bifidobacterium longum, in children with ulcerative colitis

Design
A double-blinded, randomized (Using block randomization), sham-controlled clinical trial with a parallel group design will be done on 60 patients.

Settings and conduct
Eligible patients in Namazi hospital and Imam Reza clinic will be admitted. After randomization, they will be divided into 2 groups and receive a drug or placebo for 8 weeks. Physicians, researchers, and patients will be unaware of the enema content and only the producer knows it. During and at the end of the trial, patients will be evaluated for PUCAI, laboratory findings, and adverse effects.

Participants/Inclusion and exclusion criteria
Patients between 4-20 years will be admitted to the study, who had a confirmed diagnosis of acute UC with mild to moderate disease activity (PUCAI=10-64). Exclusion criteria include: Crohn's disease Infectious colitis or other causes of colitis such as medical drugs, radiation, ischemia of affected intestinal segments Participation in another clinical trial either simultaneously or within 30 days prior to enrolment Use of antibiotics or sulfonamides within or 2 weeks prior to the study Lack of cooperation, neurotic personality, and obesity History of stool incontinence, perianal fistulae, major colonic surgery, colorectal carcinoma, or stenosis Ill patients who are unable to cooperate & the patients suspicious to toxic megacolon

Intervention groups
The intervention group receives 40 ml rectal enema containing probiotics along with standard therapy with oral mesalazine. The control group receives an identical enema preparation devoid of the active substance (probiotics) as a placebo.

Main outcome variables
Number of patients who are in remission or experience clinical response after trial

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20130514013321N3**
Registration date: **2023-07-09, 1402/04/18**
Registration timing: **registered_while_recruiting**

Last update: **2023-07-09, 1402/04/18**
Update count: **0**

Registration date
2023-07-09, 1402/04/18

Registrant information
Name
Ahmad Gholami
Name of organization / entity
Shiraz University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 71 1242 4255
Email address
gholami@sums.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-06-22, 1402/04/01
Expected recruitment end date
2024-12-21, 1403/10/01
Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A double-blind randomized clinical trial for the effectiveness of rectal enema containing a probiotic strain of Bifidobacterium longum in children with distal ulcerative colitis

Public title

Probiotic rectal enema in ulcerative colitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

children at age of 4-20 definite diagnosis of ulcerative colitis by colonoscopy and histology with disease severity of mild to moderate at least 2 confirmed prior manifestations of the disease

Exclusion criteria:

Infectious colitis or other causes of colitis such as medical drugs, radiation, ischemia of affected intestinal segments Crohn's disease Participation in another clinical trial either simultaneously or within 30 days prior to enrolment a lack of cooperation, neurotic personality, and obesity A history of stool incontinence, perianal fistulae, major colonic surgery, colorectal carcinoma, or or stenosis Ill patients who are unable to cooperate & the patients suspicious to toxic megacolon

Age

From **4 years** old to **20 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be done using block randomization with block size:4, blocked tables are determined priorly by computer software and patients will be added to the table according to the sequence of enrollment into the study and will be allocated to groups A or B. Also, they receive a number according to the table. The producer group allocates group A or B to the "drug" or "placebo" group but they don't reveal this matter until the end of the study. Delivery of the drug or placebo to the patients will be done based on the received number by each patient, so the researcher, physician, and patient are unaware of the content.

Blinding (investigator's opinion)

Double blinded

Blinding description

Eligible patients will be enrolled and randomized to treatment with either 40ml probiotics or a placebo. Patients will receive a number and will to allocated to groups A or B using a predetermined block randomization table and the order of enrolment. The producer group allocates group A or B to the "drug" or "placebo" group but they don't reveal this matter until the end of the study. Delivery of the drug or placebo to the patients will be done based on the received number by each patient. Therefore blinding of the investigator, physician, and patient will be ensured by the provision of study medication identical in appearance, and a patient-specific number.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of shiraz university of medical sciences

Street address

Administration Building of Shiraz University of Medical Sciences Zand St., Shiraz, Iran

City

Shiraz

Province

Fars

Postal code

71348-14336

Approval date

2023-05-29, 1402/03/08

Ethics committee reference number

IR.SUMS.MED.REC.1402.080

Health conditions studied

1

Description of health condition studied

ulcerative colitis

ICD-10 code

K51

ICD-10 code description

Ulcerative colitis

Primary outcomes

1

Description

Number of patients who are in clinical remission after the trial

Timepoint

At the begining of study, at the physician visits in weeks 2, 4 and 8 & patient self-reported questionnares in weeks 1,3,5,6 and 7

Method of measurement

Assessment of PUCAI by questionnaire (Clinical remission defined as PUCAI less than 10)

2

Description

Number of patients who experience clinical response after the trial

Timepoint

At the physician visits on weeks 2, 4 and 8 & patient self-reported questionnares in weeks 1,3,5,6 and 7

Method of measurement

Assessment of PUCAI by questionnaire (Clinical response defined as changes in PUCAI more than or equal to 20 or achievement of clinical remission)

Secondary outcomes

1

Description

Changes in the level of stool calprotectin

Timepoint

At the physician visits in weeks 2, 4, and 8

Method of measurement

Stool sample

2

Description

Changes in the level of inflammatory factors (ESR, CRP)

Timepoint

At the physician visits in weeks 2, 4, and 8

Method of measurement

Blood sample

3

Description

Extraintestinal manifestations

Timepoint

At the physician visits in weeks 2, 4, and 8

Method of measurement

Questionnaire

4

Description

Global health assessment by the physician

Timepoint

At the physician visits in weeks 1, 2, and 8

Method of measurement

questionnaire (6-point scale)

Intervention groups

1

Description

Intervention group: The investigational drug contains probiotic, non-pathogenic Bifidobacterium longum. (108 viable microorganisms per ml). Other components are purified water, sodium chloride, potassium chloride, magnesium sulfate, and magnesium chloride. 40 ml drug is administered as an enema at 10 o'clock. The patients receive the enema along with the standard therapy with oral mesalazine.

Category

Treatment - Drugs

2

Description

Control group: As placebo an identical enema preparation devoid of the active substance, will be used. The patients receive the enema along with the standard therapy with oral mesalazine.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Namazi hospital

Full name of responsible person

Dr. Naser Honar

Street address

Namazi hospital, Namazi square, Zand steet, Shiraz, Fars

City

Shiraz

Province

Fars

Postal code

7193613311

Phone

+98 71 3647 4332

Fax

+98 71 3647 4326

Email

nemazee_inf@sums.ac.ir

Web page address

https://namazi.sums.ac.ir/

2

Recruitment center

Name of recruitment center

Imam Reza clinic

Full name of responsible person

Dr. Naser Honar

Street address

Imam Reza clinic, Namazi square, Shiraz

City
Shiraz
Province
Fars
Postal code
7134814734
Phone
+98 71 3212 7001
Email
emamreza@sums.ac.ir
Web page address
https://emamreza.sums.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr. Mohammad Hashem Hashempur
Street address
Administration Building of Shiraz University of Medical Sciences, Zand St., Shiraz, Iran
City
Shiraz
Province
Fars
Postal code
1433671348
Phone
+98 71 3230 5410
Email
info@sums.ac.ir
Web page address
https://www.sums.ac.ir/
Grant name
Grant code / Reference number
27047
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Dr. Ahmad Gholami
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Pharmaceutical biotechnology
Street address
School of Pharmacy, Karafarin avenue
City
Shiraz
Province
Fars
Postal code
7146864685
Phone
+98 71 1242 4255
Fax
+98 71 1242 4881
Email
gholami@sums.ac.ir
Web page address
https://pharmacy.sums.ac.ir/

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr. Ahmad Gholami
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Pharmaceutical biotechnology
Street address
School of Pharmacy, Karafarin avenue
City
Shiraz
Province
Fars
Postal code
7146864685
Phone
+98 71 1242 4255
Fax
+98 71 1242 4881
Email
gholami@sums.ac.ir
Web page address
https://pharmacy.sums.ac.ir/

Person responsible for updating data

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person

Dr. Ahmad Gholami

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Pharmaceutical biotechnology

Street address

School of Pharmacy, Karafarin avenue

City

Shiraz

Province

Fars

Postal code

7146864685

Phone

+98 71 1242 4255

Fax

+98 71 1242 4881

Email

gholami@sums.ac.ir

Web page address

https://pharmacy.sums.ac.ir/

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

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

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

Title and more details about the data/document

The obtained data and the reports will be written, revised, and submitted to a peer-reviewed international journal after completing the clinical trial. The data files will be available 6 months after publication in valid international journals only for the people working in academic and scientific centers by sending an email to Dr. Saeideh Mohammadi (student researcher)

When the data will become available and for how long

The data files will be available 6 months after publication

To whom data/document is available

The data are available only for the people working in academic and scientific centers

Under which criteria data/document could be used

Repeated measure analysis of findings to evaluate the effects of the drug in longer periods of time and more detailed studies, as well as systematic reviews

From where data/document is obtainable

by sending an e-mail to Dr.Saeideh Mohammadi email address: mohammadi.saeideh2018@gmail.com

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

The request will be responded 1 week after sending an email to Dr. Saeideh Mohammadi

Comments