Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 2026

Effect of Probiotic Supplementation on Hospital Length of Stay and Clinical Outcomes in Children with Acute Gastroenteritis: A Randomized Double-Blind Placebo-Controlled Trial

Protocol summary

Study aim
To evaluate the effect of probiotic supplementation on hospital stay duration and clinical outcomes in hospitalized children with acute gastroenteritis

Design
A randomized, double-blind, parallel-group, placebo-controlled clinical trial with a 1:1 allocation ratio. Participants will be allocated using block randomization with a fixed block size of 4. The randomization unit is the individual participant, and allocation concealment will be performed using sequentially numbered, opaque, sealed envelopes.

Settings and conduct
The study will be conducted at, Motahari Hospital, UMSU. Eligible children with acute gastroenteritis will be enrolled after eligibility assessment and written informed consent from parents or legal guardians. Participants will be randomly assigned to probiotic or placebo groups in a 1:1 ratio, with both groups receiving standard treatment. Participants, parents or legal guardians, healthcare providers, outcome assessors, and the statistician will be blinded to group allocation.

Participants/Inclusion and exclusion criteria
Children aged 6 months to 5 years with acute gastroenteritis requiring hospitalization, acute diarrhea with or without vomiting, and moderate to severe dehydration; chronic renal, hepatic, metabolic, or gastrointestinal diseases, known immunodeficiency, probiotic use within the last 6 months, concurrent participation in another clinical trial, and lack of parental consent were considered exclusion criteria

Intervention groups
The intervention group will receive probiotic supplementation in addition to standard treatment for acute gastroenteritis. The control group will receive placebo in addition to standard treatment. The probiotic and placebo will be identical in appearance, color, packaging, and administration method.

Main outcome variables
Hospital stay duration; diarrhea frequency; vomiting frequency; fever; abdominal pain; dehydration severity

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20260723070318N1**
Registration date: **2026-08-24, 1405/06/02**
Registration timing: **prospective**

Last update: **2026-08-24, 1405/06/02**
Update count: **0**
Registration date
2026-08-24, 1405/06/02

Registrant information
Name
Sarvin Pashapour
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 44 3224 1967
Email address
sarvin.pashapour@gmail.com

Recruitment status
Not yet recruiting
Funding source

Expected recruitment start date
2026-09-23, 1405/07/01
Expected recruitment end date
2027-03-20, 1405/12/29
Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Probiotic Supplementation on Hospital Length of Stay and Clinical Outcomes in Children with Acute Gastroenteritis: A Randomized Double-Blind Placebo-Controlled Trial

Public title

Effect of Probiotic Supplementation in Children with Acute Gastroenteritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Children aged 6 months to 5 years with acute gastroenteritis requiring hospitalization, diagnosed based on clinical symptoms including acute diarrhea with or without vomiting, and moderate to severe dehydration. Written informed consent from parents or legal guardians is required.

Exclusion criteria:

Children with chronic renal, hepatic, metabolic or gastrointestinal diseases, known immunodeficiency, previous probiotic use within the last 6 months, concurrent participation in another clinical trial, and lack of parental consent.

Age

From **6 months** old to **5 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible participants will be randomly allocated to the intervention and control groups in a 1:1 ratio using block randomization with a fixed block size of 4. The random allocation sequence will be generated by Random Allocation Software. Individual participants will be considered as the randomization unit. The generated allocation sequence will be concealed using sequentially numbered, opaque, sealed envelopes prepared by an independent person who is not involved in participant recruitment or outcome assessment. The envelopes will be opened only after participant enrollment, confirmation of eligibility criteria, and completion of baseline assessment to ensure allocation concealment.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants, their parents or legal guardians, healthcare providers responsible for patient care, outcome assessors, and the statistician will be blinded to the assigned intervention. The probiotic and placebo will be identical in appearance, color, packaging, and administration method. Only the person responsible for preparing and dispensing the intervention will have access to the randomization codes. The allocation codes will remain confidential until completion of data collection and statistical analysis.

Placebo

Used

Assignment

Parallel

Other design features

This is a randomized, double-blind, placebo-controlled parallel clinical trial. Eligible children will be randomly assigned in a 1:1 ratio to receive either probiotic supplementation or placebo in addition to standard treatment for acute gastroenteritis. The primary outcome is hospital stay duration. Secondary outcomes include diarrhea frequency, vomiting frequency, fever, abdominal pain, and dehydration severity.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Urmia University of Medical Sciences

Street address

Research and Technology Deputy, Urmia University of Medical Sciences, Orzhans Alley, Resalat Street, Urmia, Iran

City

Urmia

Province

West Azarbaijan

Postal code

571478334

Approval date

2026-07-01, 1405/04/10

Ethics committee reference number

IR.UMSU.REC.1405.109

Health conditions studied

1

Description of health condition studied

Acute Gastroenteritis

ICD-10 code

A09

ICD-10 code description
Infectious gastroenteritis and colitis, unspecified

Primary outcomes

1

Description
Length of hospital stay
Timepoint
From hospital admission to discharge
Method of measurement
Recording the duration of hospitalization based on medical records and calculating the number of hospitalization days

Secondary outcomes

1

Description
Frequency of diarrhea episodes
Timepoint
Daily from study enrollment until hospital discharge
Method of measurement
Recording the number of watery or loose stool episodes per 24 hours based on reports from parents or legal guardians and medical records

2

Description
Frequency of vomiting episodes
Timepoint
Daily from study enrollment until hospital discharge
Method of measurement
Recording the number of vomiting episodes per 24 hours based on reports from parents or legal guardians and medical records

3

Description
Presence of fever
Timepoint
Daily from study enrollment until hospital discharge
Method of measurement
Measurement of body temperature using a standard medical thermometer and recording the presence or absence of fever in medical records

4

Description
Abdominal pain
Timepoint
Daily from study enrollment until hospital discharge
Method of measurement
Assessment of the presence or absence of abdominal pain based on clinical examination by the physician and reports from parents or legal guardians

5

Description
Severity of dehydration
Timepoint
At study enrollment and daily until hospital discharge
Method of measurement
Assessment of dehydration severity based on clinical signs including mental status, thirst, oral mucosal condition, capillary refill, pulse, and vital signs by the treating physician

Intervention groups

1

Description
Intervention group: Children with acute gastroenteritis will receive probiotic supplementation in addition to standard treatment. The probiotic supplement will be administered according to the study protocol during the hospitalization period.
Category
Treatment - Drugs

2

Description
Control group: Children with acute gastroenteritis will receive placebo in addition to standard treatment. The placebo will be identical to the probiotic supplement in appearance and administration method.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Motahari Hospital, Urmia University of Medical Sciences, Urmia
Full name of responsible person
Sarvin Pashapour
Street address
Shahid Motahari Hospital, Ayatollah Kashani Street, Three-way Kashani, opposite Aria Hotel, Urmia, West Azerbaijan Province, Iran.
City
Urmia
Province
West Azarbaijan
Postal code
5714615463
Email
Sarvin.pashapour@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Oroumia University of Medical Sciences

Full name of responsible person
Hamid Reza Khalkhali

Street address
Research and Technology Deputy, Urmia University of Medical Sciences, Orzhans Alley, Resalat Street

City
Urmia

Province
West Azarbaijan

Postal code
5756115111

Phone
+98 44 3275 0001

Email
info@umsu.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Oroumia 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
Oroumia University of Medical Sciences

Full name of responsible person
Sarvin Pashapour

Position
Faculty Member / Assistant Professor /Pediatrician

Latest degree
Specialist

Other areas of specialty/work
Pediatrics

Street address
Shahid Motahari Hospital, Urmia University of Medical Sciences, Urmia, West Azerbaijan, Iran

City
Urmia

Province
West Azarbaijan

Postal code
5714615463

Phone
+98 44 3275 0001

Email
Sarvin.pashapour@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Oroumia University of Medical Sciences

Full name of responsible person
Sarvin Pashapour

Position
Faculty Member / Assistant Professor / Pediatrician

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Specialist

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Street address
Shahid Motahari Hospital, Urmia University of Medical Sciences, Urmia, West Azerbaijan, Iran

City
Urmia

Province
West Azarbaijan

Postal code
5714615463

Phone
+98 44 3275 0001

Email
Sarvin.pashapour@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Oroumia University of Medical Sciences

Full name of responsible person
Sarvin Pashapour

Position
Assistant professor

Latest degree
Specialist

Other areas of specialty/work
Pediatrics

Street address
Kashani Street, Motahari Hospital

City
Urmia

Province
West Azarbaijan

Postal code
5714615463

Phone
+98 44 3224 1967

Fax

Email
Sarvin.pashapour@gmail.com

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Study protocol, statistical analysis plan, informed consent form, clinical study report, individual participant data (IPD), and supporting study documentation. The shared materials will include the final study protocol, statistical analysis plan, anonymized individual participant-level data, final clinical study report, and related methodological documents generated during the clinical trial.

When the data will become available and for how long

Access to the study documents and data will become available after publication of the primary results of the trial. The materials will be available beginning 6 months after publication of the main study findings and will remain accessible for at least 5 years.

To whom data/document is available

Qualified researchers, including researchers affiliated with academic institutions, research organizations, and other scientific institutions, may request access to the available study materials. Requests will be evaluated based on scientific relevance and compliance with ethical requirements.

Under which criteria data/document could be used

The shared data and documents may be used for scientifically valid research purposes, including secondary analyses, validation of published findings, and evidence synthesis. Users must ensure appropriate ethical approval when required, maintain data confidentiality, and agree not to attempt participant re-identification.

From where data/document is obtainable

Requests for access should be submitted to the corresponding author or principal investigator of the study through the official institutional email address.

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

Requests will be reviewed by the study investigators. The review process will include assessment of the scientific purpose, feasibility of the proposed analysis, ethical considerations, and compliance with data protection requirements. Approved requests will receive access after completion of the required administrative procedures and signing of a data use agreement when applicable.

Comments

All shared datasets will be de-identified before release. Access to individual participant data will comply with ethical principles, participant confidentiality requirements, and applicable regulations.