

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Determining the effect of probiotics on acute diarrhea in hospitalization children

Protocol summary

Study aim

Determining the effect of probiotics on acute diarrhea in hospitalization children

Design

The study will be double blind and clinical trial. 116 patients will be randomly divided into 2 groups. The groups are parallel. The trial phase is 3

Settings and conduct

Children with acute diarrhea admitted to Amir Kabir Hospital in Arak city are divided into 2 groups by simple randomization using the block method. The study is not blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Hospitalized patients with acute diarrhea with moderate dehydration and severe dehydration, non-bloody diarrhea, age between 6 months and 60 months, absence of any history of chronic disease, not taking antibiotics in the last two weeks, lack of immunity, not taking immunosuppressive drugs
Exclusion criteria: Unwillingness to continue studying

Intervention groups

Intervention group: patients will receive procid capsules containing 3.5 x 10⁹ Lactobacillus acidophilus, 1 x 10⁹ Lactobacillus rhamnosus, 1 x 10⁹ Bifidobacterium bifidum, and maltodextrin. Control group: patients will receive serum therapy.

Main outcome variables

Number of times of diarrhea, consistency of stool, duration of hospitalization, duration of diarrhea

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221108056433N1**

Registration date: **2022-11-26, 1401/09/05**

Registration timing: **prospective**

Last update: **2022-11-26, 1401/09/05**

Update count: **0**

Registration date

2022-11-26, 1401/09/05

Registrant information

Name

Mohammadreza Shakoori

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4447 4449

Email address

shakour111@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-01, 1401/09/10

Expected recruitment end date

2023-12-01, 1402/09/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Determining the effect of probiotics on acute diarrhea in hospitalization children

Public title

Determining the effect of probiotics on acute diarrhea in hospitalization children

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Hospitalized patients with acute diarrhea with moderate dehydration
Hospitalized patients with acute diarrhea with severe dehydration
Non-bloody diarrhea
Age between 6 months and 60 months
Absence of any history of chronic disease
Not taking antibiotics in the last two weeks
Lack of immunity
Not taking immunosuppressive drugs

Exclusion criteria:

Unwillingness to continue studying

Age

From **6 months** old to **60 months** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **116**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be allocated into 2 groups using a permuted balanced block randomization method with the size of blocks 4 and 8. Random sequence will be generated by an epidemiologist by running an online program in sealed envelope website (<https://www.sealedenvelope.com/>). Random chain concealment is done by opaque envelope method.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics cCommittee of Arak University of Medical Sciences

Street address

Ethics committee, Research center, Payambar Azam complex, Basij squire ,Sardasht,Arak

City

Arak

Province

Markazi

Postal code

3848176941

Approval date

2022-09-04, 1401/06/13

Ethics committee reference number

IR.ARAKMU.REC.1401.180

Health conditions studied

1

Description of health condition studied

Acute diarrhea

ICD-10 code

K52.9

ICD-10 code description

Noninfective gastroenteritis and colitis, unspecified

Primary outcomes

1

Description

Number of times of diarrhea

Timepoint

Before and after treatment

Method of measurement

Physical examination

2

Description

Consistency of stool

Timepoint

Before and after treatment

Method of measurement

Physical examination

3

Description

Duration of hospitalization

Timepoint

Duration study

Method of measurement

Observation

4

Description

Duration of diarrhea

Timepoint

Duration study

Method of measurement

Physical examination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: ptients will receive procid capsules containing 3.5 x 10⁹ Lactobacillus acidophilus, 1 x 10⁹

Lactobacillus rhamposus, 1 x 10⁹ Bifidobacterium bifidium, and maltodextrin.

Category

Treatment - Drugs

2**Description**

Control group: patients will receive serum therapy.

Category

Treatment - Drugs

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

Amirkabir hospital

Full name of responsible person

Dr Mojtaba Hashemi

Street address

Amirkabir hospital, Parastar square, Arak

City

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3814957558

Phone

+98 912 250 3276

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mojtaba53hashemi@yahoo.com

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

Arak University of Medical Sciences

Full name of responsible person

Dr Mehdi Salehi

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Research Center, Payambar Azam Complex, Basij square, Sardasht, Arak

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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

Arak 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**

Arak University of Medical Sciences

Full name of responsible person

Dr Nooshin Sajadi

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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

Arak University of Medical Sciences

Full name of responsible person

Dr Mojtaba Hashemi

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Person responsible for updating data

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Mohammadreza Shakoori

Position

Resident of infant

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

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Phone

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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