

# 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 10<sup>9</sup> Lactobacillus acidophilus, 1 x 10<sup>9</sup> Lactobacillus rhamnosus, 1 x 10<sup>9</sup> 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 10<sup>9</sup> Lactobacillus acidophilus, 1 x 10<sup>9</sup>

Lactobacillus rhamposus, 1 x 10<sup>9</sup> 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**

Arak

**Province**

Markazi

**Postal code**

3814957558

**Phone**

+98 912 250 3276

**Email**

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

**Street address**

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

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**Phone**

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salegi@arakmu.ac.ir

**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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Amirkabir hospital, Parastar square, Arak

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**Postal code**

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**Phone**

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**Email**

mojtaba53hashemi@yahoo.com

**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

**Street address**

No.46, East Ordibehesht, Sardarejangan, Tehran

**City**

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**Province**

Markazi

**Postal code**

3814957558

**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