

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

16 Sep 2026

### The effect of probiotics in prevention of dysentery in children

#### Protocol summary

##### Summary

Objective: The effect of probiotics in prevention of dysentery in children. Study is a randomized, double-blind intervention study (RCT). Inclusion criteria: children 6 months to 6 years old who elapsed times of the day in kindergartens of Arak will be entered in study. There will be no gender restrictions. Kindergartens of Arak, some will be selected randomly. Participants were randomly divided into two groups. The first group, five days a week for 3 months will receive probiotic: 10\*\* billion cfu Lactobacillus a dose of powder. The second group will receive placebo as powdered gelatin. The sample size in each group will be 100 peoples. Probiotic and placebo will be divide two groups: powder A and powder B. To observe the blindness of those distributing the drug / placebo and also Participants will not be informed of the nature of powders. Then all the subjects during the 3-month incidence of dysentery cases will be assessed. The group receiving drug and group receiving placebo in each nursery case to case will be match. Exclusion criteria: Children who have any medical condition (including a history of previous lasted diarrhea, malabsorption problems, intestinal polyps, the malnutrition, immune deficiency, a history of Consumption of probiotic compounds, inflammatory bowel disease or chronic disease of the small intestine) or recent (within one month before the study) received antibiotics, the children use antibiotic during taking probiotic or concurrent with other diseases or parental consent to discontinue their cooperation in the project. Children with diarrhea if they need to receive antibiotics and supportive therapy, weight loss over 10% and or requiring hospitalization will be treatment. Time of intervention will be from 03 April 2012 to 05 July 2012. The above informations for each patient individually will be analyzed.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201109267647N1**

Registration date: **2012-04-10, 1391/01/22**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2012-04-10, 1391/01/22

##### Registrant information

###### Name

Mehrnaz Adib

###### Name of organization / entity

Arak university of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 86 1313 5075

###### Email address

adib@arakmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Arak University of Medical Sciences

##### Expected recruitment start date

2012-04-03, 1391/01/15

##### Expected recruitment end date

2012-07-05, 1391/04/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of probiotics in prevention of dysentery in children

##### Public title

The effect of probiotics in prevention of dysentery in children

**Purpose**  
Prevention

**Inclusion/Exclusion criteria**  
Inclusion criteria: children 6 months to 6 years old who elapsed times of the day in kindergartens Arak will be entered in this study. There will be no gender restrictions. Kindergartens of Arak, some will be selected randomly. Exclusion criteria: children who have any underlying medical condition (including a history of previous lasted diarrhea, malabsorption problems, intestinal polyps, the malnutrition, immune deficiency, a history of Consumption of probiotic compounds, inflammatory bowel disease or chronic disease of the small intestine) or recent (within one month before the study) received antibiotics, the children who use antibiotic during taking probiotic or concurrent with other diseases (concomitant illness) or parental consent to discontinue their cooperation in the project.

**Age**  
From **1 year** old to **6 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **200**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**

**Placebo**  
Used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Arak university of Medical Sciences

##### Street address

Arak university of Medical Sciences, Pardis site, Sardasht, Beseig square, Po Box(1884)

##### City

Arak

##### Postal code

3848176941

#### Approval date

2011-08-15, 1390/05/24

## Ethics committee reference number

90-111-9

## Health conditions studied

### 1

#### Description of health condition studied

Dysentery

#### ICD-10 code

A09.9

#### ICD-10 code description

Gastroenteritis and colitis of unspecified origin

## Primary outcomes

### 1

#### Description

Dysentery

#### Timepoint

During the 3-month intervention

#### Method of measurement

Stool Exam or visible blood in the stool

## Secondary outcomes

### 1

#### Description

prevention of dysentery

#### Timepoint

during the 3-month intervention

#### Method of measurement

probability of giving dysentery

## Intervention groups

### 1

#### Description

Intervention group : five days a week for 3 months with a dose of 10 billion CFU

#### Category

Prevention

### 2

#### Description

Control group: placebo (gelatin powder)

#### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

kindergartens of Arak city, Iran

##### Full name of responsible person

Mehrnaz Adib

**Street address**

Iran-Markazi province-Arak-Amirkabir Hospital

**City**

Arak

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Arak university of Medical Sciences

**Full name of responsible person**

Saiid Changizi Ashtiani

**Street address**

Arak university of Medical Sciences,Pardis site,Beseij square,Po Box(1884)

**City**

Arak

**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**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Manijeh Kahbazi

**Position**

Assistant professor

**Other areas of specialty/work**

**Street address**

Arak university of Medical sciences,Infectious diseases & tuberculosis researchs center

**City**

Arak

**Postal code**

38196011870

**Phone**

+98 86 1313 5075

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m\_kahbazi77@yahoo.com

**Web page address**

**Person responsible for scientific inquiries**

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**Full name of responsible person**

Manijeh Kahbazi

**Position**

Assistant professor

**Other areas of specialty/work**

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Mehrnaz Adib

**Position**

Residence of Pediatric Diseases

**Other areas of specialty/work**

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**Email**

mehrnaz\_adib@yahoo.com

**Web page address**

**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*  
**Clinical Study Report**  
*empty*  
**Analytic Code**

*empty*  
**Data Dictionary**  
*empty*