

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### The effect of probiotic compared with placebo on the duration of dysentery in hospitalized patients

#### Protocol summary

##### Summary

This study is a clinical trial on 100 patients admitted in Pediatrics or Infectious Diseases Wards of Shahid Beheshti Hospital with complaints of fever and bloody diarrhea in 2014. Dysentery is confirmed by stool exam. Patients with severe malnutrition, immune deficiency or using of anti-diarrheal drugs are excluded from the study. Patients randomly assign into two groups. Experimental group receive probiotic as Kidilact prepared by Zist Khavar Company and the control group will receive placebo prepared by Farabi Co. They receive these products every 12 hours for 5 days. Treatment protocols for dysentery shall be conducted in two groups. Duration of fever and bloody diarrhea and hospitalization will be recorded by the question of patients and study of dossier.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014060617985N1**

Registration date: **2014-10-26, 1393/08/04**

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

Last update:

Update count: **0**

##### Registration date

2014-10-26, 1393/08/04

##### Registrant information

###### Name

Alireza Sharif

###### Name of organization / entity

Kashan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 5554 0026

###### Email address

sharif\_a@kaums.ac.ir

###### Recruitment status

**Recruitment complete**

###### Funding source

Kashan University of Medical Sciences

###### Expected recruitment start date

2014-10-23, 1393/08/01

###### Expected recruitment end date

2015-10-23, 1394/08/01

###### Actual recruitment start date

empty

###### Actual recruitment end date

empty

###### Trial completion date

empty

###### Scientific title

The effect of probiotic compared with placebo on the duration of dysentery in hospitalized patients

###### Public title

The effect of probiotic on improvement of dysentery

###### Purpose

Treatment

###### Inclusion/Exclusion criteria

Inclusion criteria: Patients hospitalized with fever and bloody diarrhea in pediatrics or infectious diseases wards; Active stool exam  
Exclusion criteria: Severe malnutrition; Immune deficiency; Using of anti-diarrheal drugs

###### Age

From **2 years** old

###### Gender

Both

###### Phase

N/A

###### Groups that have been masked

No information

### Sample size

Target sample size: **100**

### 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

Kashan University of Medical Sciences

##### Street address

Kashan University of Medical Sciences, Ghotbe  
Ravandi Blvd, Kashan, Iran

##### City

Kashan

##### Postal code

#### Approval date

2014-10-15, 1393/07/23

#### Ethics committee reference number

134

## 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

Fever improvement

#### Timepoint

Every 6 hours

#### Method of measurement

Mercury thermometer

### 2

#### Description

Stop bloody diarrhea

#### Timepoint

Daily

#### Method of measurement

Stool chart

### 3

#### Description

Duration of diarrhea

#### Timepoint

Daily

#### Method of measurement

Stool chart

## Secondary outcomes

### 1

#### Description

Duration of hospital stay

#### Timepoint

At discharge

#### Method of measurement

Study of records

## Intervention groups

### 1

#### Description

Intervention group: Oral administration of probiotic (Kidilact) every 12 hours for 5 days

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Oral administration of placebo (like probiotic) every 12 hours for 5 days

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shahid Beheshti Hospital

##### Full name of responsible person

Dr. Alireza Sharif

##### Street address

Shahid Beheshti Hospital, Ghotbe Ravandi Blvd,  
Kashan, Iran

##### City

Kashan

## Sponsors / Funding sources

## 1

### Sponsor

**Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

Dr. Gholam Ali Hamidi

**Street address**

Kashan University of Medical Sciences, Ghotbe  
Ravandi Blvd, Kashan, Iran

**City**

Kashan

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Kashan 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**

### Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

Dr. Mohammad Reza Sharif

**Position**

Associate Professor, Pediatric Infectious Diseases  
Subspecialist

**Other areas of specialty/work****Street address**

Kashan University of Medical Sciences, Ghotbe  
Ravandi Blvd, Kashan, Iran

**City**

Kashan

**Postal code****Phone**

+31 55540026

**Fax**

+98 31 5554 8900

**Email**

mrsharifmd@yahoo.com

**Web page address**

www.drsharif.ir

### Person responsible for updating data

**Contact****Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

Dr. Mohammad Reza Sharif

**Position**

Associate Professor, Pediatric Infectious Diseases  
Subspecialist

**Other areas of specialty/work****Street address**

Kashan University of Medical Sciences, Ghotbe  
Ravandi Blvd, Kashan, Iran

**City**

Kashan

**Postal code****Phone**

+98 31 5554 0026

**Fax**

+98 31 5554 8900

**Email**

mrsharifmd@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*