

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

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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**

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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