

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

Comparing the effect of conventional and probiotic yogurts on duration of acute watery diarrhea in children

Protocol summary

Summary

This study is a clinical trial on 90 children aged 1-5 years admitted to pediatric clinic in Kashan Beheshti Hospital with complaints of acute watery diarrhea. Children with high fever ($T > 38.5^{\circ}\text{C}$), severe dehydration, bloody diarrhea, severe malnutrition, using of antibiotics, anti-diarrheal or anti-fungal drugs and patients with more than one complain or Immune deficiency are excluded from the study. Patients randomly assign into three groups. Experimental group1 receive conventional yogurt prepared by Pak Company 15 ml/kg/day for 5 days and experimental group 2 receive probiotic yogurt prepared by Pak Company 15 ml/kg/day for 5 days and the control group will receive no yogurt. In three groups, treatment protocols for acute watery diarrhea (using ORS) shall be conducted. Frequency and duration of diarrhea within the past 24 hours is recorded by asking mothers.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014081311145N12**

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

Mohammad Reza Sharif

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 5554 0026

Email address

sharif_m@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

2015-08-23, 1394/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of conventional and probiotic yogurts on duration of acute watery diarrhea in children

Public title

The effect of conventional and probiotic yogurts on acute watery diarrhea in children

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Children admitted to pediatric clinic in Kashan Beheshti Hospital with complaints of acute watery diarrhea; Aged 1-5 years Exclusion criteria: High fever ($T > 38.5^{\circ}\text{C}$); Severe dehydration; Bloody diarrhea; Severe malnutrition; Using of antibiotics, anti-diarrheal or anti-fungal drugs; Patients with more than one complain; Immune deficiency

Age

From **1 year** old to **5 years** old

Gender

Both	Stool chart
Phase N/A	2
Groups that have been masked No information	Description Frequency of diarrhea
Sample size Target sample size: 90	Timepoint Daily
Randomization (investigator's opinion) Randomized	Method of measurement Counting the number of stools
Randomization description	
Blinding (investigator's opinion) Not blinded	Secondary outcomes empty
Blinding description	
Placebo Not used	Intervention groups
Assignment Parallel	1
Other design features	Description Intervention group 1: Oral administration of conventional yogurt, 15 mg/kg daily for 5 days plus ORS
Secondary Ids empty	Category Treatment - Drugs
Ethics committees	2
1	Description Intervention group 2: Oral administration of probiotic yogurt, 15 mg/kg daily for 5 days plus ORS
Ethics committee	Category Treatment - Drugs
Name of ethics committee Kashan University of Medical Sciences	
Street address Kashan University of Medical Sciences, Ghotbe Ravandi Blvd, Kashan, Iran	3
City Kashan	Description Control group: Administration of ORS without yogurt
Postal code	Category Treatment - Drugs
Approval date 2014-10-15, 1393/07/23	
Ethics committee reference number 134/	Recruitment centers
Health conditions studied	1
1	Recruitment center
Description of health condition studied Acute watery diarrhea	Name of recruitment center Shahid Beheshti Hospital
ICD-10 code A09.9	Full name of responsible person Dr.Mohammad Reza Sharif
ICD-10 code description Gastroenteritis and colitis of unspecified origin	Street address Shahid Beheshti Hospital, Ghotbe Ravandi Blvd, Kashan, Iran
Primary outcomes	City Kashan
1	Sponsors / Funding sources
Description Duration of diarrhea	1
Timepoint Daily	Sponsor
Method of measurement	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****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

8714753371

Phone

+98 31 5554 0026

Fax

+98 31 5554 8900

Email

mrsharifmd@yahoo.com

Web page address

www.drsharif.ir

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

8714753371

Phone

+98 31 5554 0026

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

8714753371

Phone

+98 31 5554 0026

Fax

+98 31 5554 8900

Email

mrsharifmd@yahoo.com

Web page address

www.drsharif.ir

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