Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effect of bacterial and yeast probiotics on acute watery diarrhea in children

Protocol summary

Summary

This study is a clinical trial on 90 children aged 2-5 years admitted to pediatric clinic in Kashan Beheshti Hospital with complaints of acute watery diarrhea. Children with high fever (T>38.5°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 Kidilact as a bacterial probiotic prepared by Zist Khavar Company and experimental group 2 receive Saccharomyces boulardii as a yeast probiotic prepared by Ardegpharm-GmbH and the control group will receive placebo prepared by Farabi Co.Placebo and probiotics have similar color and taste. They receive these products once daily for 5 days. In three groups, treatment protocols for watery acute 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: **IRCT2013031511145N6**
Registration date: **2013-08-31, 1392/06/09**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-08-31, 1392/06/09

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

2013-08-23, 1392/06/01

Expected recruitment end date

2014-05-22, 1393/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of bacterial and yeast probiotics on acute watery diarrhea in children

Public title

The effect of bacterial and yeast probiotics 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 2 - 5 years. Exclusion criteria: High fever (T>38.5°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 **2 years** old to **5 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single 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

5th Kilometer, Ghotbe Ravandi Bulv, Kashan

City

Kashan

Postal code

8715988141

Approval date

2013-08-25, 1392/06/03

Ethics committee reference number

2040/1/5/29پ

Health conditions studied

1

Description of health condition studied

Acute Watery Diarrhea

ICD-10 code

A09.9

ICD-10 code description

Gastroenteritis and colitis of unspecified origin

Primary outcomes

1

Description

Stop Diarrhea

Timepoint

Daily

Method of measurement

Asking from mother

2

Description

Duration of diarrhea

Timepoint

Daily

Method of measurement

Asking from mother

3

Description

Frequency of Diarrhea

Timepoint

Daily

Method of measurement

Asking from mother

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 2:Oral administration of yeast probiotic (Saccharomyces boulardii) daily + ORS

Category

Treatment - Drugs

2

Description

Control group: Oral administration of placebo (like probiotics) daily + ORS

Category

Treatment - Drugs

3

Description

Intervention group 1: Oral administration of bacterial probiotic (Kidilact) daily + ORS

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Beheshti Hospital

Full name of responsible person

Dr.Mohammad Reza Sharif

Street address

Beheshti Hospital, 5th Kilometer, Ghotbe Ravandi

Bulv, Kashan

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, 5th Kilometer, Ghotbe Ravandi Bulv, Kashan

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

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Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

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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