

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Investigating the effect of Kidi Lact probiotic supplement administration on the symptoms of diarrhea and dehydration caused by gastroenteritis in children

Protocol summary

Study aim

Investigating the effect of KidiLact probiotic supplementation on the symptoms of diarrhea and dehydration caused by gastroenteritis in children referred to Amir-al-Momenin Hospital in Semnan in different seasons of the year.

Design

The clinical trial has a control group with parallel groups, double-blind, randomized, phase 3 on 400 patients.

Settings and conduct

This study is a Triple-blind clinical trial study that examines children suffering from gastroenteritis referred to Amir-al Momenin Hospital in Semnan. The sampling method is based on the available sample and the number of 400 referring children will be examined if they meet the inclusion criteria and do not have the exclusion criteria. Patients, researchers, data collectors and data analysts are unaware of the study conditions.

Participants/Inclusion and exclusion criteria

Inclusion criteria: children aged 12 to 72 months, suffering from acute gastroenteritis . Exclusion criteria: Gastroenteritis patients who are older than 6 years and less than one year old.

Intervention groups

The samples are randomly divided into two groups: case and control, half of which will be examined in the control group and half in the case group. The control group will be children with gastroenteritis who will receive a placebo, and the case group will be children with gastroenteritis who will receive the probiotic supplement Kid Locket for 10 days.

Main outcome variables

Severity of dehydration, frequency of diarrhea

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20241029063537N1**
Registration date: **2025-01-14, 1403/10/25**
Registration timing: **prospective**

Last update: **2025-01-14, 1403/10/25**

Update count: **0**

Registration date

2025-01-14, 1403/10/25

Registrant information

Name

Houman Parsaei

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-03-21, 1404/01/01

Expected recruitment end date

2026-03-21, 1405/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of Kidi Lact probiotic supplement

administration on the symptoms of diarrhea and dehydration caused by gastroenteritis in children

Public title

Investigating the effect of probiotics in gastroenteritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Consent to participate in a research project Suffering from acute gastroenteritis and signs and symptoms of acute non-bloody diarrhea, and mild to moderate dehydration that have an indication for liquid therapy Refer to the medical center within the first 72 hours from the onset of symptoms.

Exclusion criteria:

Unwillingness to participate in a research project Gastroenteritis patients who are more than 6 years old and less than one year old Children who have been sick for more than 72 hours Children with chronic gastrointestinal disease (such as inflammatory bowel disease and Celiac disease), severe malnutrition (grade 2 and 3), pancreatic insufficiency Children with underlying diseases such as allergy to probiotic products Children with kidney failure, chronic lung diseases, congenital heart failure and clear neurological disease Children who receive antibiotics or acid-blocking drugs or who have taken probiotics for any reason within a week before entering the study. Change in treatment due to new diagnosis, treatment in the form of receiving serum in medical centers before going to Amir--al-Momenin Hospital The existence of unexplained abnormal findings in the urine sample

Age

From **12 months** old to **72 months** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **400**

Randomization (investigator's opinion)

Randomized

Randomization description

In the block randomization method, considering blocks of 4, among the 6 possible states for blocks of four including two people from the intervention group (A) and two people from the control group (B): (1.AABB, 2.ABAB, 3.BBAA, 4.BABA, 5.ABBA, 6.BAAB), Using the RANDBETWEEN(1,6) command in Excel software, the number of blocks corresponding to the sample size will be randomly selected, and a random allocation sequence will be created. The participants are equally divided into intervention and control groups based on the established allocation sequence. The randomization sequence will be placed in sealed, opaque envelopes to ensure allocation

concealment. These envelopes are numbered in sequence and will be opened by the person responsible for allocation only after the participant has accepted the study.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Patients, researchers, data collectors and data analysts are unaware of the study conditions. The placebo and the drug will be the same in terms of appearance, taste and method of administration.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Semnan University of Medical Sciences

Street address

Semnan - Golestan town - above Al-Ghadir Square - Kausar Hospital

City

Semnan

Province

Semnan

Postal code

3519899558

Approval date

2024-07-08, 1403/04/18

Ethics committee reference number

IR.SEMUMS.REC.1403.053

Health conditions studied

1

Description of health condition studied

Gastroenteritis

ICD-10 code

A08

ICD-10 code description

Viral and other specified intestinal infections

Primary outcomes

1

Description

Severity of dehydration

Timepoint

The beginning and end of the study

Method of measurement

Urine test (BUN, Creatinine, and urine specific gravity); blood test (sodium and potassium); clinical symptoms (nurse's report and child's mother's report)

Secondary outcomes

1

Description

Frequency of diarrhea

Timepoint

The beginning and end of the study

Method of measurement

The report of the nurse and the report of the child's mother

Intervention groups

1

Description

Intervention group: Kidi Lact Sachet is an unflavored edible sachet containing safe and beneficial bacterial strains and prebiotic fructooligosaccharide (FOS). The company that manufactures the drug is Zist Takhmir. The case group will be children with gastroenteritis, who will receive Kidi Lact probiotic supplement for 10 days and one sachet per day.

Category

Treatment - Drugs

2

Description

Control group: Children with gastroenteritis will receive a placebo. The placebo will be prepared by the Zist Takhmir drug manufacturer, and the way to use it is the same as how to use the medicine.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir al-Momenin (AS) educational, research and treatment center

Full name of responsible person

Morteza Rezaei

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Semnan - Golestan town - above Al-Ghadir Square - Kausar Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Abbas Ali Wafai

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Semnan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Houman Parsaie

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Anatomy

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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Full name of responsible person

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available