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

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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
Street address
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

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Person responsible for updating data

Contact
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Semnan University of Medical Sciences
Full name of responsible person
Bita Salehi
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Student
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Other areas of specialty/work
General Practitioner
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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