

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Evaluation and comparison of the effect of oral vitamin D and probiotics on acute non-inflammatory diarrhea in children 6 months to 6 years

Protocol summary

Study aim

Comparison of the effect of oral vitamin D and probiotics on acute non-inflammatory diarrhea in children 6 months to 6 years

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 2 on 186 patients. For randomization, three cards with letters A, B and C are placed in front of the patient and the patient selects one. Each letter belongs to one of three groups used

Settings and conduct

Sealed coded packages are provided to the resident and design partner to provide the drug to the patient based on the code and provide the necessary explanations to the mothers.

Participants/Inclusion and exclusion criteria

Admission criteria: Age 1 to 5 years with acute watery diarrhea. Exclusion criteria: fever above 38.5; severe dehydration; severe diarrhea; severe malnutrition; recent use of antibiotics or antidiarrheal drug; having another complaint in addition to watery diarrhea with immunodeficiency.

Intervention groups

Intervention group 1: The group under one year of age should take 5 drops of paddy lactate 5 drops every 8 hours and 1 to 2 years of Kidi Lactate powder 1/2 cup every 12 hours and over 2 years 1 pint every 12 hours. Intervention group 2: Vitamin D3 supplement group in the form of 800 units of 20 mg daily can be placed under two years due to 400 units of vitamin D drops in 400 units and over 2 years of dose 800 units of vitamin D3 to this group. 7 days control: This group is only allowed as a control group

Main outcome variables

Stool consistency; number of stools; duration of diarrhea; fever, anorexia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210615051584N1**

Registration date: **2021-07-04, 1400/04/13**

Registration timing: **registered_while_recruiting**

Last update: **2021-07-04, 1400/04/13**

Update count: **0**

Registration date

2021-07-04, 1400/04/13

Registrant information

Name

Manige Ahmadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 38 3222 0016

Email address

ahmadi.ma@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-17, 1400/03/27

Expected recruitment end date

2021-07-23, 1400/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation and comparison of the effect of oral vitamin D and probiotics on acute non-inflammatory diarrhea in children 6 months to 6 years

Public title

The effect of probiotics and vitamin D on diarrhea in children

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Acute acute watery diarrhea

Exclusion criteria:

Fever above 38.5 degree Centigrade Severe dehydration Severe diarrhea Severe malnutrition Recent use of antibiotics or antidiarrheal drug Having another complaint in addition to watery diarrhea with immunodeficiency

Age

From **6 months** old to **6 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **186**

Randomization (investigator's opinion)

Randomized

Randomization description

Three cards with the letters A, B and C are placed in front of the patient and the patient chooses one. Each letter belongs to one of three groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patient and the evaluating physician are unaware of the study groups

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Shahrekord University of Medical Sciences

Street address

Shahrekord University of Medical Sciences, Kashani St.

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8818863472

Approval date

2020-06-30, 1399/04/10

Ethics committee reference number

IR.SKUMS.REC.1399.102

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**

Number of times diarrhea

Timepoint

Daily to 7 Day

Method of measurement

Question from the sick mother

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group 1: the group under one year of age should take 5 drops of paddy lactate 5 drops every 8 hours and 1 to 2 years of Kidi Lactate powder 1/2 cup every 12 hours and over 2 years 1 pint every 12 hours. Intervention group 2: Vitamin D3 supplement group in the form of drops of 800 units of 20 mg daily can be under two years due to 400 units of vitamin D drops in the case of 400 units and over 2 years of 800 units of oral vitamin D3 for 7 days

Category

Treatment - Drugs

2**Description**

Control group: this group receives only placebo as a control group for 7 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hajar Hospital, Shahrekord

Full name of responsible person

Dr. Ali Asghar Rabiee

Street address

Hajar Hospital Nurse Street

City

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Chahar-Mahal-va-Bakhtiari

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8816754633

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a.rabiei@skums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Mehraban Sadeghi

Street address

Kashani St. Shahrekord University of Medical Sciences

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Email

mehr.sadeghi1ir@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahre-kord 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

Shahre-kord University of Medical Sciences

Full name of responsible person

Manigeh Ahmadi

Position

Associate

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

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Nurse Street

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Dr. Aliasghar Rabiee

Position

Consultant

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Latest degree

Specialist

Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

Some of the forgotten theory is related to the main message that can be divided.

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

Only for researchers working in academic institutions

Under which criteria data/document could be used

Researchers who are writing meta-analysis articles

From where data/document is obtainable

Email address

What processes are involved for a request to access data/document

After sending the email via academic email and the reason for the need for data, this study will be provided to the researcher within a week.

Comments