

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

The study on the efficacy of available synbiotics in Iran(KidiLacts and PediLacts) on the decrease in duration of acute diarrhea in 6 month to 5 years old outpatients in comparison with standard treatment

Protocol summary

Summary

The purpose of this double-blind randomized clinical trial(control with standard treatment, phase 3) is studying on the efficacy of synbiotics (probiotic plus prebiotic including KidiLacts and PediLacts) available in Iran on decrease in duration of acute diarrhea in 6 -month to 5 - years -old outpatients. 100 children suffering from acute diarrhea with non-bloody diarrhea whose dehydration is mild to moderate is going to be subjected to the study.(A check list of demographic information and clinical presentation will be given to parents). They are going to be divided into two 50 persons groups (6-month to 2-year-old and 2-year to 5-year-old). PediLact plus ORS randomly will be prescribed to 25 persons of 6 month to 2 year old's group , 10 drops daily till 5 day and KidiLact plus ORS randomly will be prescribed to 25 persons of 2 year to 5 year old's group, 1 sachet daily till 5 day. 50 persons of controlled group will just receive oral rehydration with ORS as the recommendation of WHO protocols(the intervention groups receive ORS as the same too). Five days later, all the patients are going to be called asking for their physical conditions; if diarrhea is recuperated, if so, its time duration of suffering will be submitted otherwise they will be daily followed up till absolute recovery. Then the comparison between two groups will be done.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017071935178N1**

Registration date: **2017-09-23, 1396/07/01**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-09-23, 1396/07/01

Registrant information

Name

Mitra Aldaghi

Name of organization / entity

Sabzevar University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 514411071

Email address

aldaghim@medsab.ac.ir

Recruitment status

Recruitment complete

Funding source

Sabzevar University of Medical Science

Expected recruitment start date

2017-02-19, 1395/12/01

Expected recruitment end date

2017-08-22, 1396/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The study on the efficacy of available synbiotics in Iran(KidiLacts and PediLacts) on the decrease in duration of acute diarrhea in 6 month to 5 years old outpatients in comparison with standard treatment

Public title

Efficacy of Synbiotics (KididLact and PediLact) in the treatment of acute diarrhea

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Signed informed consent form by patient's parents ; Patients between 6 months to 5 years old; Patients with acute diarrhea(less than 14 days).

Exclusion criteria: Unwillingness of keeping the research up in any point with any excuse; Patient had severe diarrhea or need venous rehydratin; Patient had chronic diarrhea(more than 14 days); Consuming precedent of antibiotic in this diarrhea cycle; Presence of bloody diarrhea; Age less than 6 months or more than 5 years; Kid suffering from FTT(Failure To Thrive);The patient involved with other organs' infections (Otitis, Pneumonia, Urinary Tract Infection and etc); The patient has utilized probiotics during a week ago; History of any kind of cancer in the past; Immunocompromised

Age

From **6 months** old to **5 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Sabzevar University of Medical Science

Street address

Sabzevar University of Medical Science, Tohid town, Sabzevar

City

Sabzevar

Postal code

Approval date

2017-03-13, 1395/12/23

Ethics committee reference number

IR.MEDSAB.REC.1395.143

Health conditions studied

1

Description of health condition studied

Diarrhea

ICD-10 code

A08

ICD-10 code description

Other gastroenteritis and colitis of infectious and unspecified origin

Primary outcomes

1

Description

Duration of diarrhea

Timepoint

5 days after intervention and if diarrhea continues; daily

Method of measurement

Day

Secondary outcomes

1

Description

Advers effect of drug

Timepoint

End of intervention

Method of measurement

Clinical evaluation

Intervention groups

1

Description

Intervention group: First group recieve 1 suchet of Kidilact (for 2 to 5 years old) which is contains 1 gram of 10*9 microorganism, daily for 5 days. For each patient 5 suchet has been considered.

Category

Treatment - Drugs

2

Description

Intervention group: Second group receive synbiotic of Pedilact (for 6 months to 2 years old) as 10 drops per day until 5 days. Pedilact is a oral drops which contain 15 cc in a bottle with 10*9 microorganism. For each patient one bottle has been considered.

Category

Treatment - Drugs

3

Description

Control group: Standard oral rehydration therapy with powder of ORS(in 1 liter cold boiled water). 10 cc per

kilogram after each time of defecation until end of recuperation time

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinic of Special and Subspecial Heshmatie Hospital

Full name of responsible person

Zohre Nazemi

Street address

Clinic of Special and Subspecial Heshmatie Hospital,
Asad abadi street, Sabzevar

City

Sabzevar

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Sabzevar University of
Medical Science

Full name of responsible person

Hamidreza Baghani Aval

Street address

Vice chancellor for research, Sabzevar University of
Medical Science, Tohid town, Sabzevar

City

Sabzevar

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Sabzevar University of
Medical Science

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

Medical University of Medical Science

Full name of responsible person

Zohre Nazemi

Position

Medical Student

Other areas of specialty/work

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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