Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 May 2026

Evaluation the efficacy of the probiotic (Ramnuflor and sabular) on acute diarrhea in six months to five –year- old children referred to Heshmatieh Hospital.

Protocol summary

Study aim

1.Determining the therapeutic effect of rhenofluor probiotic for acute diarrhea in children 6 months to 2 years old referred to Heshmatieh Hospital. 2.Determining the therapeutic effect of subular probiotic on acute diarrhea in children aged 2 to 5 years referred to Heshmatieh Hospital.

Design

Clinical trial has two intervention groups and one control group. With parallel groups. Shift method sampling of 180 people sample size.

Settings and conduct

Heshmatieh Hospital. Rhenofluor probiotic for children 6 months to 2 years and subdural for 2 to 5 years.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Children 6 months to 5 years with acute diarrhea. Exclusion criteria: 1. Clinical and laboratory symptoms based on chronic diarrhea. 2. Diarrhea lasts more than 7 days. 3. Be over 5 years old or under 6 months old. 4. The patient has a known case of immunodeficiency or cancer or a known underlying disease. 5. The patient has FTT or has a known chronic disease. 6. Weight less than 3% percentile 8. The patient has been taking probiotics for the past week. 9. Diarrhea accompanied by involvement or infection of other examined organs.

Intervention groups

Study groups: Group 1, children 6 months to 2 years old receiving rhinofluor probiotic (n = 45) Group 2. Children 2 to 5 years old receiving subular probiotics (n = 45) Group 3, group receiving routine treatment (90 patients including 45 children 6 months to 2 years old and 45 children 2 to 5 years old)

Main outcome variables

Duration of recovery from acute diarrhea

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210312050687N1**
Registration date: **2021-05-14, 1400/02/24**
Registration timing: **registered_while_recruiting**

Last update: **2021-05-14, 1400/02/24**
Update count: **0**

Registration date

2021-05-14, 1400/02/24

Registrant information

Name

Fateme Hamedifar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 4333 2760

Email address

f.hamedifar2019@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-21, 1400/02/01

Expected recruitment end date

2021-07-23, 1400/05/01

Actual recruitment start date

2021-04-21, 1400/02/01

Actual recruitment end date

2021-07-23, 1400/05/01

Trial completion date

2021-10-23, 1400/08/01

Scientific title
Evaluation the efficacy of the probiotic (Ramnuflor and sabular) on acute diarrhea in six months to five –year-old children referred to Heshmatieh Hospital.

Public title
Evaluation the efficacy of the probiotic (Ramnuflor and sabular) on acute diarrhea in six months to five –year-old children referred to Heshmatieh Hospital.

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Clinical and laboratory symptoms based on chronic diarrhea. Diarrhea lasted more than 7 days. Be over 5 years old or under 6 months old The patient has a known case of immunodeficiency or cancer or a known underlying disease. Have an FTT or have a known chronic illness. Weight less than 3% percentile The patient has been taking probiotics for the past week Diarrhea accompanied by involvement or infection of other examined organs. Severe electrolyte disturbances such as hypernatremia, sodium betasherazine 145 and hypocalcemia, potassium less than 3.5 Dehydration percentage more than 10%

Exclusion criteria:

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

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **180**
Actual sample size reached: **180**

Randomization (investigator's opinion)
Randomized

Randomization description
With the easy sampling method, the qualified patients referred to Heshmatieh Hospital are randomly divided into three groups (2 intervention and control) after selecting the sample. In this study, individuals were assigned to 3 groups using permutation block method. In this method, A represents the individual receiving the first intervention, B represents the individual receiving the second intervention, and C represents the individual in the control group. After entering the study, they will enter one of the three study groups using the six-block random method. A set of different modes, BBCAAC BCAACB, CCAABB خواهد will be prepared by a statistician. Using the letters A, B and C will be considered as a symbol of one of the three intervention groups. Each of the six codes is enclosed in a sealed envelope that cannot be read from the envelope. At the patients' visit, one of the envelopes is randomly selected and the patients are assigned to one of the study groups in the order of the letters mentioned in it. Therefore, by selecting the numbers from the table, the method of assigning a total of 180 people to the three groups will be determined.

Blinding (investigator's opinion)
Double blinded

Blinding description
Using permutation block sampling method. Two-way blind The researcher (person implementing the project) and the people participating in the project are unaware of the type of treatment.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee Sabzevar University of Medical Sciences

Street address
Asad abadi St.olom pezeshki sabzevar

City
Sabzevar

Province
Razavi Khorasan

Postal code
9333156683

Approval date
2021-03-10, 1399/12/20

Ethics committee reference number
IR. MEDSAB. REC. 1399.194

Health conditions studied

1

Description of health condition studied
Acute diarrhea

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Number of times diarrhea per day

Timepoint
For 7 days in a row

Method of measurement
interview

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Group one. Group of children 6 months to 2 years receiving probiotic rhamnofluor. 45 people. This group receives standard ORS and Zinc fluid therapy along with 5 mm drops of Ramenofluor with a daily dose of 10 drops for 7 days. Raminoflor probiotic drops are from Farabiotic Company.
Category
Treatment - Drugs

2

Description
Intervention group:Group 2. Children 2 to 5 years old receiving subular probiotics. 45 people. This group, in addition to the standard fluid therapy, ORS and Zinc, receive one subular sachet daily for 7 days. Sapolar sac is from a parabiotic company that dissolves in liquid or solid food.
Category
Treatment - Drugs

3

Description
Control group:The group receiving routine diarrhea treatment included 45 children aged 6 months to two years and 45 children aged 2 to 5 years. This group receives standard ORS and Zinc fluid therapy.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Heshmatieh Hospital Sabzevar
Full name of responsible person
Fateme hamedifar
Street address
Asad abadi St,Heshmatieh Hospital Sabzevar
City
Sabzevar
Province
Razavi Khorasan
Postal code
9333156684
Phone
+98 51 4401 1600
Fax
Email
f.hamedifar2019@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Sabzevar University of Medical Sciences
Full name of responsible person
Mohamad hosin saghi
Street address
Asad abadi St, Olom pezeshki sabzevar
City
Sabzevar
Province
Razavi Khorasan
Postal code
9333156683
Phone
+98 51 4401 1000
Email
f.hamedifar2019@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Sabzevar 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
Heshmatieh Hospital sabzevar
Full name of responsible person
Mehdi jalili akbarian
Position
Pediatrician
Latest degree
Specialist
Other areas of specialty/work
Pediatrics
Street address
Asad abadi St,Heshmatieh Hospital sabzevar
City
Sabzevar
Province
Razavi Khorasan
Postal code
9333156683
Phone

+98 51 4401 1600

Email

jalilim56@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Mehdi jalili akbarian

Position

Pediatrician

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

Street address

Asad abadi St, Heshmatieh Hospital sabzevar

City

Sabzevar

Province

Razavi Khorasan

Postal code

9333156683

Phone

+98 51 4401 1600

Email

jalilim56@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Fatemeh hamedifar

Position

Medical student

Latest degree

A Level or less

Other areas of specialty/work

Others

Street address

Asad abadi St,Heshmatieh Hospital sabzevar

City

Sabzevar

Province

Razavi Khorasan

Postal code

9333156683

Phone

+98 51 4333 2760

Email

f.hamedifar2019@gmail.com

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