# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 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