

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 2026

### Probiotic prophylaxis to prevent ventilator-associated pneumonia in children on mechanical ventilation: A randomized double-blind clinical trial

#### Protocol summary

##### Study aim

Investigate the incidence of ventilator associated pneumonia in children on mechanical ventilation

##### Design

A randomized blinded placebo-controlled trial on 200 pediatric patients on mechanical ventilation

##### Settings and conduct

The randomization has been performed using the permuted block randomization table. The medication and placebo will be in look-alike coded packages. The codes based on the permuted block randomization table will be provided to the researcher by a designated person via phone. The study is conducted on 200 pediatric patients admitted to Mofid children hospital pediatric intensive care unit (PICU) under mechanical ventilation. All children entering the PICU are monitored and enrolled if they meet the inclusion criteria. Intervention group: In addition to routine interventions to prevent ventilator-associated pneumonia (VAP), patients will receive the probiotic sachet twice daily, and in the control group, in addition to receiving common interventions, they will receive probiotic-free sachets. Patients will be monitoring for VAP daily. Patients' demographic information, including age, sex, indication for mechanical ventilation and the pediatric risk of mortality (PIM-3) score, will be recorded for all patients and evaluated in case of VAP.

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria: age between 28 days to 12 years, children who were likely to require mechanical ventilation for more than 48 h; Exclusion Criteria: underlying immunodeficiency, paralytic ileus, gastrointestinal bleeding

##### Intervention groups

Intervention group: In addition to routine interventions to prevent VAP, patients will receive the Lactobacillus rutri probiotic sachet twice daily, and in the control group, in addition to receiving routine interventions, they will

receive probiotic-free sachets.

##### Main outcome variables

Incidence of ventilator associated pneumonia (VAP)

#### General information

##### Reason for update

The manuscript of this RCT was accepted.

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20120415009475N9**

Registration date: **2021-05-30, 1400/03/09**

Registration timing: **registered\_while\_recruiting**

Last update: **2022-11-04, 1401/08/13**

Update count: **1**

##### Registration date

2021-05-30, 1400/03/09

##### Registrant information

###### Name

Bahador Mirrahimi

###### Name of organization / entity

Shahid Beheshti University of Medical Sciences,  
Faculty of Pharmacy

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 8820 0118

###### Email address

mirrahimi@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-05-22, 1400/03/01

##### Expected recruitment end date

2022-05-22, 1401/03/01  
**Actual recruitment start date**  
2021-05-22, 1400/03/01  
**Actual recruitment end date**  
2022-07-09, 1401/04/18  
**Trial completion date**  
2022-07-23, 1401/05/01

**Scientific title**  
Probiotic prophylaxis to prevent ventilator-associated pneumonia in children on mechanical ventilation: A randomized double-blind clinical trial

**Public title**  
Evaluation of Probiotic Efficacy in Prevention of Ventilator Associated Pneumonia

**Purpose**  
Prevention

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Age between 28 days to 12 years Children who were likely to require mechanical ventilation for more than 48 h  
**Exclusion criteria:**  
Underlying immunodeficiency Paralytic ileus  
Gastrointestinal bleeding

**Age**  
From **28 days** old to **12 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Data analyser

**Sample size**  
Target sample size: **200**  
Actual sample size reached: **72**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
The randomization has been performed using the permuted block randomization table. The block randomization method is designed to randomize subjects into groups that result in equal sample sizes. This method is used to ensure a balance in sample size across groups over time. In our study, subjects will be randomized in 4 patient blocks. Randomization was centralized and computerized with a concealed randomization sequence carried out at <https://www.sealedenvelope.com/>.

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
The medication and placebo will be in look-alike coded packages, and the codes based on the permuted block randomization table will be provided to the researcher by a designated person via phone. At the end of the study, after organizing the data by the same person, the

statistical expert will perform the analysis. Then, the code packet will be opened, and the final results will be reported.

**Placebo**  
Used  
**Assignment**  
Parallel  
**Other design features**

**Secondary Ids**  
empty

## Ethics committees

1

### Ethics committee

**Name of ethics committee**  
institutional ethics committee for Pharmacy, Nursing and Midwifery Schools  
**Street address**  
2nd floor, School of Nursing and Midwifery, Valiasr and Niayesh junction

**City**  
Tehran

**Province**  
Tehran

**Postal code**  
1546815514

**Approval date**  
2021-03-07, 1399/12/17

**Ethics committee reference number**  
IR.SBMU.PHARMACY.REC.1399.383

## Health conditions studied

1

### Description of health condition studied

Ventilator-associated Pneumonia

### ICD-10 code

J95.851

### ICD-10 code description

Ventilator associated pneumonia

## Primary outcomes

1

### Description

Incidence of ventilator associated pneumonia

### Timepoint

14 days after intubation

### Method of measurement

Chest x-ray, Clinical sign and Lab Data

## Secondary outcomes

## 1

### Description

Duration of ICU stay

### Timepoint

Daily

### Method of measurement

Day

## 2

### Description

Duration of Mechanical Ventilation

### Timepoint

Daily

### Method of measurement

Day

## Intervention groups

### 1

#### Description

Intervention group: In addition to routine interventions to prevent VAP, patients will receive the Lactobacillus rutri probiotic sachet twice daily.

#### Category

Prevention

### 2

#### Description

Control group: In addition to receiving routine interventions, they will receive probiotic-free sachets.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Mofid children's Hospital

##### Full name of responsible person

Bahador Mirrahimi

##### Street address

Mofid Children's Hospital, Mirdamad Junction, Shariaty Ave.

##### City

Tehran

##### Province

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##### Postal code

1546815514

##### Phone

+98 21 2222 7029

##### Email

mirrahimi@sbmu.ac.ir

##### Web page address

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Dr. Seyed Ali Ziaee

##### Street address

3rd Floor, Faculty of medicine, Arabi Ave, Daneshjoo Blvd, Velenjak.

##### City

Tehran

##### Province

Tehran

##### Postal code

1985717443

##### Phone

+98 21 2243 2040

##### Email

mpd@sbmu.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Soheil Roshanzamiri

##### Position

Clinical Pharmacy Resident

##### Latest degree

Specialist

##### Other areas of specialty/work

Medical Pharmacy

##### Street address

School of Pharmacy, Shahid Beheshti University of Medical Sciences, Niayesh junction, Valiasr Ave, Tehran, Iran

##### City

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##### Province

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**Phone**

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**Email**

Roshanzamirisoheil@gmail.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Dr. Bahador Mirrahimi

**Position**

Asistant Profesor, Pharmacotherapy.

**Latest degree**

Specialist

**Other areas of specialty/work**

Medical Pharmacy

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Mofid children's Hospital, Miradmad Junction, Shariaty Ave.

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mirrahimi@sbmu.ac.ir

**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Dr. Bahador Mirrahimi

**Position**

Asistant Profesor, Pharmacotherapy.

**Latest degree**

Specialist

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

Mofid children's Hospital, Miradmad Junction, Shariaty Ave.

**City**

Tehran

**Province**

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**Postal code**

1546815514

**Phone**

+98 21 2222 7020

**Fax****Email**

mirrahimi@sbmu.ac.ir

**Web page address****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**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

The main outcome will be available.

**When the data will become available and for how long**

Six months after publishing.

**To whom data/document is available**

The data will be available per request for people working in academic institutions.

**Under which criteria data/document could be used**

The data will available for using in systematic review and meta-analysis.

**From where data/document is obtainable**

The data will be available by contacting email; mirrahimi@sbmu.ac.ir.

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

The data will available for using in systematic review and meta-analysis.

**Comments**