

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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)

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+98 21 8820 0118

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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

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

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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.

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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

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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

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