Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 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)

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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
Street address
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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1985717443
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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
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Position
Clinical Pharmacy Resident
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Specialist
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