Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Study of the effect of symbiotics on preventing ventilator- associated pneumonia in children on mechanical ventilation

Protocol summary

Study aim
The study of the effect of synbiotics on prevention of VAP in children on mechanical ventilation

Design
This clinical trial has control group without blinding, phase 3 on 35 patients in sample group and 35 patients on control group with non-random sampling method with the use of national code. Children with even national code are put in patient group and children with odd national code are put in control group.

Settings and conduct
This study is done at PICU in Imam Hossein Children's Hospital, Isfahan, Iran. After choosing the patient group, KidiLact is orally prescribed twice a day during seven days.

Participants/Inclusion and exclusion criteria
The studied population are the children aged from 1 month old to 9 years old who are on mechanical ventilation in PICU. Inclusion criteria is the children who needs mechanical ventilation for more than 48 hours and without primary immunodeficiency. Non-inclusion criteria is children with primary immunodeficiency.

Intervention groups
The patient group are children on mechanical ventilation who are prescribed synbiotics and the control group are the children on mechanical ventilation who receives nothing.

Main outcome variables
Reduction of VAP; reduction of the length of VAP treatment; reduction of the length of mechanical ventilation; reduction of ICU stay; reduction of hospital stay; reduction of mortality

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220912055944N1**
Registration date: **2023-05-04, 1402/02/14**
Registration timing: **prospective**

Last update: **2023-05-04, 1402/02/14**
Update count: **0**

Registration date
2023-05-04, 1402/02/14

Registrant information

Name
Hanieh Basirkazeruni

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-05-10, 1402/02/20

Expected recruitment end date
2024-05-09, 1403/02/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Study of the effect of symbiotics on preventing ventilator- associated pneumonia in children on mechanical ventilation

Public title
Study of the effect of symbiotics on preventing

ventilator- associated pneumonia

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Children supported by mechanical ventilation for at least 48 hours and without primary immunodeficiency

Exclusion criteria:

Primary immunodeficiency

Age

From **1 month** old to **9 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

In this study, the intervention group receives the drug and the control group receives nothing

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Esfahan University of Medical Sciences, Hezar Jarib Ave.

City

Esfahan

Province

Isfehan

Postal code

81746-73461

Approval date

2022-06-27, 1401/04/06

Ethics committee reference number

IR.MUI.MED.REC.1401.135

Health conditions studied

1

Description of health condition studied

Ventilator-associated pneumonia

ICD-10 code

J20-J22

ICD-10 code description

Other acute lower respiratory infections

2

Description of health condition studied

Duration of mechanical ventilation

ICD-10 code

ICD-10 code description

3

Description of health condition studied

Duration of ICU stay

ICD-10 code

ICD-10 code description

4

Description of health condition studied

Duration of hospital stay

ICD-10 code

ICD-10 code description

5

Description of health condition studied

Mortality rate

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Percentage of patients who were infected with ventilator-associated pneumonia

Timepoint

At the beginning, middle and the end of the study

Method of measurement

Nonbronchoscopic bronchoalveolar lavage (NB-BAL)

Secondary outcomes

1

Description

Duration of ventilator-associated pneumonia treatment

Timepoint

Beginning and end of the treatment

Method of measurement

Number of the days that ventilator-associated pneumonia was treated

2

Description
Duration of mechanical ventilation
Timepoint
Beginning and end of the mechanical ventilation
Method of measurement
Number of the days the patients were under mechanical ventilation

3

Description
Duration of hospitalization in pediatric intensive care unit
Timepoint
Beginning and end of the hospitalization in pediatric intensive care unit
Method of measurement
Number of the days the patients were hospitalized in pediatric intensive care unit

4

Description
Duration of hospitalization
Timepoint
Beginning and end of the hospitalization
Method of measurement
Number of the days the patients were hospitalized

5

Description
Mortality rate
Timepoint
End of the study
Method of measurement
Counting the deaths

Intervention groups

1

Description
Intervention group: The patients who were put in this group prescribed KidiLact during the first 24 hour after intubation. This drug is produced by Zisttakhmir company and it includes synbiotic (peribiotic + probiotic) suitable for children up to 10 years old. It contains 10 safe and useful bacteria including the especial kind of bacteria for children called bifidobacterium infantis and fructooligosaccaride as a peribiotic. KidiLact is sold as a sachet as it can be used easily for children. It includes Lactobacilus ramnosus, Lactobacilus roteri, Lactobacilus acidophilus, Lactibacilus bulgaris, Lactobacilus kazei, Bifidobacterium infantis, Bifidobacterium berveh, Bifidobacterium bifidum, Bifidobacterium lactis, Streptococcus termophilus with the colony count of 109 and fructooligosaccaride as a peribiotic. The patients were received one sachet orally twice a day for seven days.
Category
Prevention

2

Description
Control group: The patients in this group were received nothing after mechanical ventilation.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam hossein children's hospital
Full name of responsible person
Hanieh Basirkazeruni
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Phone
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research@mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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
Esfahan University of Medical Sciences
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Hanieh Basirkazeruni
Position
Resident of fellowship
Latest degree
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
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
Title and more details about the data/document
Study of the effect of symbiotics on preventing ventilator-associated pneumonia in children on mechanical ventilation
When the data will become available and for how long
From the publication date of the article
To whom data/document is available
The researchers of the universities and research centers
Under which criteria data/document could be used
Citation of the published paper
From where data/document is obtainable
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What processes are involved for a request to access data/document

Sending an email to the corresponding author of the paper

Comments