

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 3666 4034

###### Email address

hany\_med1384@yahoo.com

##### 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**

Isfahan

##### **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 Zistakhmir 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 fructooligosaccharide as a peribiotic. KidiLact is sold as a sachet as it can be used easily for children. It includes Lactobacillus ramnosus, Lactobacillus roteri, Lactobacillus acidophilus, Lactobacillus bulgaris, Lactobacillus kazei, Bifidobacterium infantis, Bifidobacterium berveh, Bifidobacterium bifidum, Bifidobacterium lactis, Streptococcus termophilus with the colony count of 10<sup>9</sup> and fructooligosaccharide 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

##### **Street address**

Imam Hossein children's hospital, Imam khomeini Ave., Isfahan

##### **City**

Isfahan

##### **Province**

Isfahan

##### **Postal code**

8195163381

##### **Phone**

+98 31 3386 6266

##### **Email**

hany\_med1384@yahoo.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Esfahan University of Medical Sciences

##### **Full name of responsible person**

Gholamreza Asgari

##### **Street address**

Esfahan university of medical sciences, Hezar Jerib Ave., Isfahan, Iran

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##### **Province**

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##### **Postal code**

8174673461

##### **Phone**

+98 31 3668 0048

##### **Email**

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

sharareh.ba@gmail.com

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

Esfahan University of Medical Sciences

**Full name of responsible person**

Hanieh Basirkazeruni

**Position**

Student of fellowship

**Latest degree**

Specialist

**Other areas of specialty/work**

Pediatrics

**Street address**

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

Esfahan University of Medical Sciences

**Full name of responsible person**

Hanieh Basirkazeruni

**Position**

Resident of fellowship

**Latest degree**

Specialist

**Other areas of specialty/work**

Pediatrics

**Street address**

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

Esfahan University of Medical Sciences

**Full name of responsible person**

Sharareh Babai

**Position**

Assistant professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Pediatrics

**Street address**

Imam hosein children's hospital, Imam khomeini Ave.,

**City**

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**Province**

Isfahan

**Postal code**

8195163381

**Phone**

+98 31 3386 6266

**Email****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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00989133190061- sharareh.ba@gmail.com

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

Sending an email to the corresponding author of the  
paper

**Comments**