

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jul 2026

### Evaluation of phage therapy in prevention of bacterial pneumonia caused by ventilator in patients admitted to Pediatric Intensive Care Unit of BuAli Hospital of Sari

#### Protocol summary

##### Study aim

Determining the effect of phage therapy in preventing ventilator-induced bacterial pneumonia in patients hospitalized in Pediatric Intensive Care Unit

##### Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 0 on 60 patients.

##### Settings and conduct

This double-blind randomized clinical trial is conducted to prevent ventilator-induced bacterial pneumonia in patients admitted to the Pediatric Intensive Care Unit (PICU) of BuAli Hospital in Sari. Patients are randomly selected by age block and divided into two intervention and control groups in parallel. The patient and the researchers do not know the contents of the vials. Phage and placebo cocktails are prepared with the same shape and color in the laboratory of the research center by the relevant expert.

##### Participants/Inclusion and exclusion criteria

People under 18 years of age, whose reason for needing mechanical ventilation is not bacterial pneumonia and need ventilator for more than 2 days are included in the study, and people who use a ventilator for less than 48 hours and babies under 28 days old are excluded from the study.

##### Intervention groups

The intervention group receive phage cocktail with a titer of  $10^{12}$  PFU/mL every 24 hours for 20 minutes with a mesh nebulizer. The placebo group receive 10 cc of phage-free phage-based suspension every 24 hours for 20 minutes with a mesh nebulizer. Phage and placebo cocktail suspension is prepared in 10 cc vials and delivered to the nurse for use.

##### Main outcome variables

Primary outcome: positive tracheal culture or occurrence of Ventilator-induced pneumonia Secondary outcome: death or discharge from PICU or discharge or one week

after extubation Changes in the course of the patient during the hospitalization days from the start of the intervention until the end of the study will be recorded daily.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230701058628N1**

Registration date: **2023-07-18, 1402/04/27**

Registration timing: **retrospective**

Last update: **2023-07-18, 1402/04/27**

Update count: **0**

##### Registration date

2023-07-18, 1402/04/27

##### Registrant information

##### Name

Mohammad Reza Navaeifar

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 3334 2334

##### Email address

m.navaeifar@mazums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-06-24, 1400/04/03

##### Expected recruitment end date

2023-03-20, 1401/12/29

##### Actual recruitment start date

2021-06-26, 1400/04/05  
**Actual recruitment end date**  
2023-03-20, 1401/12/29  
**Trial completion date**  
empty

**Scientific title**  
Evaluation of phage therapy in prevention of bacterial pneumonia caused by ventilator in patients admitted to Pediatric Intensive Care Unit of Buali Hospital of Sari

**Public title**  
Investigating phage therapy in the prevention of ventilator-induced bacterial pneumonia in patients admitted to the pediatric intensive care unit

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Age <18 years The reason for the need for mechanical ventilation is not bacterial pneumonia need for mechanical ventilation for more than 2 days  
**Exclusion criteria:**  
Need ventilator <48 hours Neonates < 28 days

**Age**  
From **29 days** old to **18 years** old

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**

- Participant
- Care provider
- Investigator

**Sample size**  
Target sample size: **30**  
Actual sample size reached: **30**

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

**Randomization description**  
Randomization is done by simple randomization method with age block. Nebulizer solutions are prepared and coded in the laboratory by the relevant expert, and the treatment team will not know the suspension content, and only based on the initial determined group, the desired solution will be delivered to the treatment team daily. The laboratory personnel will not be informed about the patient and the treatment process.

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

**Blinding description**  
The study will be conducted in a double-blind manner, and the patient and researchers (nurses, doctors) are considered blind. Phage cocktail and placebo are prepared in exactly the same packages for nebulization, and group A and B labels are marked on the products by the co-producer of the cocktail and placebo. The laboratory colleague is not involved in the statistical analysis and checking the results.

**Placebo**  
Used

**Assignment**  
Parallel  
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Mazandaran University of Medical Sciences

##### Street address

Pediatric Infectious Diseases Research Center, Buali Hospital, Pasdaran Boulevard, Sari, Iran

##### City

Sari

##### Province

Mazandaran

##### Postal code

4815838477

#### Approval date

2021-06-23, 1400/04/02

#### Ethics committee reference number

IR.MAZUMS.REC.1400.305

## Health conditions studied

### 1

#### Description of health condition studied

Ventilator-associated Bacterial Pneumonia

#### ICD-10 code

J15

#### ICD-10 code description

Bacterial pneumonia, not elsewhere classified

## Primary outcomes

### 1

#### Description

Positive endotracheal culture

#### Timepoint

Once every three days from the time of drug nebulization

#### Method of measurement

Culture by mini-BAL (Mini bronchoalveolar lavage) method

### 2

#### Description

Occurance of Ventilator-associated pneumonia

#### Timepoint

Daily

#### Method of measurement

Fever above 38°C without any other cause or white blood cell below 4000 or leukocytosis  $\geq$  12000 white cells per

cubic millimeter and at least two cases of new purulent sputum onset, change in sputum characteristics, increased respiratory secretions or increased need for suction, onset or worsening of cough, shortness of breath or tachypnea; rales or bronchial lung sounds; Worsening of blood gases (for example, increased need for oxygen or increased ventilator settings)

## Secondary outcomes

### 1

#### Description

Death

#### Timepoint

Which day of hospitalization

#### Method of measurement

The time of death of the patient based on medical record

### 2

#### Description

Discharge from PICU or hospital

#### Timepoint

One week after extubation

#### Method of measurement

Discharge from PICU or hospital based on medical record

## Intervention groups

### 1

#### Description

Intervention group: The intervention group receives the phage cocktail made by the laboratory of the Pediatric Infectious Diseases Research Center with a titer of 10x12 PFU/mL every 24 hours for 20 minutes with a mesh nebulizer. Phage cocktail suspension is prepared in 10 cc vials and delivered to the nurse for use. The doctor and the person collecting the information do not know about placebo and phage cocktail suspension.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: The control group receives 10 cc suspension with phage composition base without phage every 24 hours for 20 minutes with mesh nebulizer device. Placebo suspension is prepared in 10 cc vials and delivered to the nurse for use. The doctor and the person collecting the information do not know about placebo and phage cocktail suspension.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

#### Name of recruitment center

Buali Hospital

#### Full name of responsible person

Dr. Mohammad Reza Navaeifar

#### Street address

Pediatric Infectious Diseases Research Center, Buali Hospital, Pasdaran Boulevard, Sari, Iran

#### City

Sari

#### Province

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4815838477

#### Phone

+98 911 325 2944

#### Email

m.navaeifar@mazums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mazandaran University of Medical Sciences

##### Full name of responsible person

Pedram Ebrahimnejad

##### Street address

Vice chancellor for Research, Moallem square, Sari, Iran

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Sari

##### Province

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##### Postal code

4712855689

##### Phone

+98 11 3448 4800

##### Email

pebrahimnejad@mazums.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Mazandaran 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**  
Mazandaran University of Medical Sciences  
**Full name of responsible person**  
Dr. Mohammad Reza Navaeifar  
**Position**  
Assistant professor  
**Latest degree**  
Subspecialist  
**Other areas of specialty/work**  
Pediatric intensive care unit fellow  
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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
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**Full name of responsible person**  
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Professor  
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## Person responsible for updating data

### Contact

**Name of organization / entity**

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**Other areas of specialty/work**  
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m.navaeifar@mazums.ac.ir

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

No - There is not a plan to make this available

### Statistical Analysis Plan

Not applicable

### Informed Consent Form

No - There is not a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

No - There is not a plan to make this available

### Data Dictionary

No - There is not a plan to make this available

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

Contact Dr.Mohammad Reza Navaeifar. Email: dr.navaifar@gmail.com

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

Informations will send within few days after the email.

### To whom data/document is available

People working in academic institutions

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

Contact Dr.Mohammad Reza Navaeifar. Email: dr.navaifar@gmail.com

### From where data/document is obtainable

Email

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

Informations will send within few days after the email.

### Comments