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

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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 ≥ 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
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Pediatric Infectious Diseases Research Center, Buali Hospital, Pasdaran Boulevard, Sari, Iran
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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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4712855689
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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
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Person responsible for scientific inquiries

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Person responsible for updating data

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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