

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### Clinical trial of evaluation of phage therapy with nebulizer in prevention of secondary bacterial pneumonia in admitted patients with moderate to severe COVID-19

#### Protocol summary

##### Study aim

Determining the effect of nebulizer phage therapy on prevention of secondary bacterial pneumonia in patients with moderate to severe COVID-19

##### Design

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

##### Settings and conduct

A double-blind randomized clinical trial will be performed on patients with COVID-19 admitted to Mazandaran teaching hospitals. Individuals are randomly selected and divided into two parallel groups of intervention and control. The patient and the researcher are unaware of the contents of the vials. Phage cocktail and placebo are prepared in the same shape and color. Only a laboratory colleague is aware of the contents of the vials which is not involved in statistical analysis and evaluation of the results.

##### Participants/Inclusion and exclusion criteria

Inclusion: Children and adults with moderate to severe COVID-19 Having one of the following symptoms: Dry cough, severe weakness and fatigue, dyspnea, chest pain, fever  $>38^{\circ}\text{C}$  Less than 3 days have passed since the first sign started Definitive diagnosis of COVID-19  
Exclusion: Patient who has previously had COVID-19 or has been hospitalized for COVID-19 Participate in any other clinical trial for the treatment of COVID-19  
Bradycardia, abnormal primary ECG Active cancer, immunodeficiency or treatment with immunosuppressive drugs Underlying liver and kidney disease

##### Intervention groups

Control group: standard treatments +10 cc phage-free suspension daily with a nebulizer Intervention group: standard treatments +10 cc phage cocktail daily with a nebulizer

##### Main outcome variables

Primary outcomes: Clinical conditions in first 10 days;

Oxygen Saturation; fever, dyspnea, cough, lung infection or recurrence of secondary lung bacterial infection  
Secondary outcomes: Survival rate, duration of hospitalization, ICU admission and ventilation

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20111224008507N6**

Registration date: **2021-05-07, 1400/02/17**

Registration timing: **prospective**

Last update: **2021-05-07, 1400/02/17**

Update count: **0**

##### Registration date

2021-05-07, 1400/02/17

##### Registrant information

##### Name

Mohammad Sadegh Rezai

##### Name of organization / entity

Mazandaran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 3334 2334

##### Email address

rezai@mazums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-05-10, 1400/02/20

##### Expected recruitment end date

2021-07-11, 1400/04/20

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Clinical trial of evaluation of phage therapy with nebulizer in prevention of secondary bacterial pneumonia in admitted patients with moderate to severe COVID-19

**Public title**

Phage therapy for prevention of secondary bacterial pneumonia in COVID-19

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Children and adults with moderate to severe COVID-19 (moderate: Evidence of pulmonary involvement or symptoms on imaging. severe: Respiratory rate more than 30 times per minute + percentage of blood oxygen saturation less than 93% + infiltration more than 50% in the lungs) Having one of the following symptoms: Dry cough, severe weakness and fatigue, dyspnea, chest pain, fever greater than 38° C Less than 3 days have passed since the first sign started Definitive diagnosis of Covid-19 based on RT-PCR test "or" Involvement of a maximum of 3 or 4 pulmonary lobes with an area less than one third of the volume of each lobe "or" Infection of one or two lobes with a larger area in the patient's CT scan view

**Exclusion criteria:**

Patient who has previously had COVID-19 or has been hospitalized for COVID-19 Participate in any other clinical trial for the treatment of COVID-19 Bradycardia, abnormal primary ECG Active cancer, immunodeficiency or treatment with immunosuppressive drugs Underlying liver and kidney disease

**Age**

From **4 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

First, using the Random number generation plugin in excel software, a table of random numbers from 1 to 60 is prepared in a non-sequential and scattered manner, and the numbers are assigned to two intervention and control groups of 30 cases. The randomization process is

performed by the methodology consultant and clinical researchers are not aware of the randomization process and will only be provided with random codes from 1 to 60.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

To increase the validity of the data obtained from the study and prevent bias, the study will be conducted in a double-blind manner. In this study, patients and researchers (nurses, physicians) do not know which group consumes phage cocktail and which group consumes non-phage suspension and are considered blind. Phage cocktail and placebo are prepared in completely uniform packages for nebulization And the group A and B labels are marked on the products by the partner who produces cocktails and placebo. The laboratory colleague is not involved in statistical analysis and review of 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**

Vice chancellor for Research, Moallem square, Sari

**City**

Sari

**Province**

Mazandaran

**Postal code**

47128-55689

**Approval date**

2021-01-04, 1399/10/15

**Ethics committee reference number**

IR.MAZUMS.REC.1399.819

**Health conditions studied****1****Description of health condition studied**

COVID-19

**ICD-10 code**

U07.1

**ICD-10 code description**

COVID-19, virus identified

## Primary outcomes

### 1

#### Description

Secondary pulmonary bacterial infection

#### Timepoint

Before the intervention and days 1 to 7, and 14 and 21 days after treatment

#### Method of measurement

Sputum culture, CT scan, clinical signs (fever, cough, ...)

## Secondary outcomes

### 1

#### Description

Blood oxygen saturation

#### Timepoint

10 and 14 days after treatment

#### Method of measurement

Paloxymeter

### 2

#### Description

Survival rate

#### Timepoint

After hospitalization

#### Method of measurement

Record of recovery or death

### 3

#### Description

Number of hospitalization days

#### Timepoint

Initiation of hospitalization until after discharge or death

#### Method of measurement

Number of days

### 4

#### Description

Number of days of intubation

#### Timepoint

Start intubation until the tube separates or death

#### Method of measurement

Number of days

### 5

#### Description

Number of days in the ICU

#### Timepoint

Start entering the ICU until discharge from the ICU

#### Method of measurement

Number of days

### 6

#### Description

Body temperature

#### Timepoint

Daily until 14 days

#### Method of measurement

Thermometer

### 7

#### Description

Cough

#### Timepoint

Daily until 14 days

#### Method of measurement

Observation and asking the patient

### 8

#### Description

Fatigue

#### Timepoint

Daily until 14 days

#### Method of measurement

Observation and asking the patient

## Intervention groups

### 1

#### Description

Intervention group: For 7 days, once daily, 10 ml of bacteriophage cocktail solution with a titer of one trillion pfu (Plaque Forming Units) per ml is nebulized once a day.

#### Category

Prevention

### 2

#### Description

Control group: For 7 days, once daily, receive 10 ml of the base suspension solution without bacteriophage cocktail as a nebulizer.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Teaching hospitals of Mazandaran

##### Full name of responsible person

Modammad Sadegh Rezai, MD

##### Street address

Bouali Hospital, Pasdaran boulevard, Sari

##### City

Sari

##### Province

Mazandaran

##### Postal code

4815838477

##### Phone

+98 11 3334 2334

**Email**

drmsrezai@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Dr. Majid Saeidi

**Street address**

Vice chancellor for Research, Moallem square, Sari

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**Province**

Mazandaran

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msaeidi@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 Sadegh Rezai

**Position**

Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Infectious diseases

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rezai@mazums.ac.ir

**Web page address**

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Mohammadsadegh Rezai

**Position**

Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Infectious diseases

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## Person responsible for updating data

#### Contact

**Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Mohammadsadegh Rezai

**Position**

Professor

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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

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

Not applicable

### Data Dictionary

Not applicable

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

Part of the data is accessible

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

starting in january 2022

### To whom data/document is available

Physicians

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

Systematic review articles

### From where data/document is obtainable

Contact Dr.Mohammad Sadegh Rezai. Email:  
drmsrezai@yahoo.com

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

Informations will send within few days after the call.

### Comments