

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Feb 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

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Bouali Hospital, Pasdaran boulevard, Sari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr. Majid Saeidi

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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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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