Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Clinical trial of ealuation 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°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; Oxigen Saturation; fever, dyspnea, cough, lung infection or recurrence of secondary lung bacterial infection Secondary outcomes: Survival rate, duration of hospitalization, ICU admition 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 ealuation 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 و ...)

Secondary outcomes

1

Description
Blood oxygen saturation
Timepoint
10 and 14 days after treatment
Method of measurement
Palsoxymeter

2

Description
Survival rate
Timepoint
After hospitalization
Method of measurement
Recoed 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 temprature
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
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4815838477
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Email

drmsrezaii@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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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 junuary 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: drmsrezaii@yahoo.com
What processes are involved for a request to access data/document
Informations will send within few days after the call.
Comments