

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the Efficacy of nebulized 5% hypertonic saline on inflammatory factors and recovery of severe pneumonia in patients with Covid-19 hospitalized in intensive care units

Protocol summary

Study aim

Determination of the effect of 5% hypertonic saline on inflammatory mediators in patients with severe pneumonia caused by Covid-19 admitted to ICU

Design

This study is a randomized controlled double-blind clinical trial.

Settings and conduct

The study will be performed in the special wards of Imam Khomeini Hospital in Tehran. The study population will be 40 male and female patients between the ages of 18 and 70 in the ICU. Patients with inclusion criteria will be randomly divided into two groups of 20 people A and B. In group A, 10 ml of 5% hypertonic saline and in group B, 10 ml of distilled water for 6 hours will be nebulized for 5 days. The person preparing the samples and performing the tests, as well as recording and following up the consequences, are separate and are not aware of the type of intervention in the patient. The patient's nurse performs nebulizes of the solution based on the codes provided to her.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with severe pneumonia caused by Covid-19 admitted to the ICU, age between 18-70 years old, Conscious consent of the patient or his/her family. Non-entry conditions: use of interleukin production inhibitors, history of immunodeficiency, active bacterial pneumonia, hypernatremia, previous thoracic and lung surgery, intubation patients

Intervention groups

Intervention group A: Nebulization of 10 ml of 5% NaCl every 6 hours. Intervention group B: Nebulization of 10 ml of distilled water every 6 hours.

Main outcome variables

Blood levels of interleukin 6; Blood levels of TNF α ; Duration of hospitalization in the ICU; death; Pao₂ / fio₂ ratio

General information

Reason for update

Acronym

COVID-19 نبولایز سالین هیپرتونیک 5% در بیماران پنومونی شدید

IRCT registration information

IRCT registration number: **IRCT20120216009045N4**

Registration date: **2021-12-01, 1400/09/10**

Registration timing: **prospective**

Last update: **2021-12-01, 1400/09/10**

Update count: **0**

Registration date

2021-12-01, 1400/09/10

Registrant information

Name

Mohammad Taghi Beigmohammadi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-11, 1400/09/20

Expected recruitment end date

2022-02-09, 1400/11/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	identical syringes. In order to double-blind the study, the syringe of each patient is delivered to the nurse based on the grouping. The person who nebulizes the solutions is not aware of the type of solution. The patient's blood sample is prepared and sent to the laboratory without knowing the type of nebulized solution. The experimenter was not aware of the grouping of patients and did not know which patient the blood sample belonged to. The researcher examines the laboratory results of each patient based on the set codes.
Scientific title Evaluation of the Efficacy of nebulized 5% hypertonic saline on inflammatory factors and recovery of severe pneumonia in patients with Covid-19 hospitalized in intensive care units	
Public title Evaluation of the effect of 5% hypertonic saline nebulization on inflammatory factors and recovery in patients with severe pneumonia caused by covid 19	
Purpose Treatment	
Inclusion/Exclusion criteria Inclusion criteria: Patient with Covid-19 coronavirus (confirmation of diagnosis by positive PCR test) Severe pneumonia due to COVID-19 Age 70 - 18 years Conscious consent of the patient or her guardian in cases that the patient is not conscious. Exclusion criteria: Receiving interleukin production inhibitors such as Octemra Patients with a history of HIV + or any history of immunodeficiency Patient with active bacterial pneumonia Primary or metastatic lung cancer History of any cancer or malignancy Chronic lung diseases include: pulmonary fibrosis, bronchiectasis, asthma smoking Previous thoracic and lung surgery Patients with hypernatremia Intubated patients	Placebo Used Assignment Parallel Other design features
Age From 18 years old to 70 years old	Secondary Ids empty
Gender Both	Ethics committees 1 Ethics committee Name of ethics committee Ethics Committee of Tehran University of Medical Sciences Street address Headquarters of Tehran University of Medical Sciences, Ghods st, keshavarz Blvd City Tehran Province Tehran Postal code ۱۴۱۷۶۵۳۷۶۱
Phase 1	Approval date 2020-05-24, 1399/03/04 Ethics committee reference number TR.TUMS.IKHC.REC.1400.016
Groups that have been masked - Investigator - Outcome assessor - Data analyser	
Sample size Target sample size: 40	
Randomization (investigator's opinion) Randomized	
Randomization description Patients with inclusion criteria were randomly divided into two groups, A and B, using a random number table. Even numbers for groups A and odd numbers will be for group B. The researcher randomly touches the table and moves the numbers from top to bottom into two groups A or B based on being even and odd. Each number will belong to a patient. Of the 40 randomly selected patients, 20 patients in group A in the intervention group will be nebulized with 10 ml of 5% hypertonic saline every 6 hours. 20 patients in group B are nebulized with 10 ml of distilled water and the two groups will be compared in terms of inflammatory factors.	Health conditions studied 1 Description of health condition studied The effect of 5% hypertonic saline on blood levels of inflammatory factors in patients with severe pneumonia caused by covid 19 ICD-10 code J12.8 ICD-10 code description Other viral pneumonia
Blinding (investigator's opinion) Double blinded	Primary outcomes 1 Description Interleukin 6 Timepoint
Blinding description The solutions are pre-prepared and coded in sterile,	

While hospitalized in the ICU for 5 days, before and after of intervention.

Method of measurement

Samples containing the biomarkers are transferred to a reference laboratory in an EDTA-containing test tube, and centrifuged at 3,000 rpm for 15 minutes. The resulting plasma for measuring IL-6, TNF- α markers is stored by the researcher at minus 80 ° C. Quantitative determination is done by the quantitative sandwich enzyme immunoassay method by Bendermed commercial kits.

2

Description

Measurement of serum TNF- α before and after the intervention.

Timepoint

During 5 days of admission in the ICU.

Method of measurement

Samples containing the biomarkers are transferred to a reference laboratory in an EDTA-containing test tube, and centrifuged at 3,000 rpm for 15 minutes. The resulting plasma for measuring IL-6, TNF- α markers is stored by the researcher at minus 80 ° C. Quantitative determination is done by the quantitative sandwich enzyme immunoassay method by Bendermed commercial kits.

Secondary outcomes

1

Description

Mortality rate in two groups

Timepoint

During admission in the ICU.

Method of measurement

Status of patient leaving ICU: alive or dead.

Intervention groups

1

Description

Intervention group: Patients receiving 10 ml, 5% hypertonic saline nebulization during ICU admission

Category

Treatment - Drugs

2

Description

Control group: Patients who receive 10 ml of distilled water through nebulization during hospitalization in the ICU.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

ICU of Imam Khomeini Hospital in Tehran

Full name of responsible person

Mohammad Taghi Beigmohammadi

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Imam Khomeini Hospital Complex, Dr.Gharib St., Keshvarz Blvd.,

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Taghi Beigmohammadi

Position

Associate professor, Head of ICUs of Imam Khomeini Hospital Complex

Latest degree

Subspecialist

Other areas of specialty/work

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Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

ICU group office, Imam Khomeini Hospital Complex, end of Keshavarz blv.

City

Tehran

Province

Tehran

Postal code

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable