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 TNFα; Duration of hospitalization in the ICU; death; Pao2 / fio2 ratio

General information

Reason for update

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

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)

Phone
+98 21 6119 2511

Email address
beigmohammadi@tums.ac.ir

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

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

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
1

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.

Blinding (investigator's opinion)
Double blinded

Blinding description
The solutions are pre-prepared and coded in sterile, 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.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

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

Approval date
2020-05-24, 1399/03/04

Ethics committee reference number
TR.TUMS.IKHC.REC.1400.016

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

Primary outcomes

1

Description
Interleukin 6

Timepoint

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 Beigmohhammadi

Street address

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

City

Tehran

Province

Tehran

Postal code

۱۴۱۹۷۳۳۱۴۱

Phone

+98 21 6119 0000

Email

mbage46@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Akbar Fotouhi

Street address

Headquarters ofTehran University of Medical Sciences,Ghods St., Keshavarz Blv.

City

Tehran

Province

Tehran

Postal code

۱۴۱۷۶۵۳۷۶۱

Phone

+98 21 8163 3561

Email

afotouhi@tums.ac.ir

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
Anesthesiology

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

City
Tehran

Province
Tehran

Postal code
1419733141

Phone
+98 21 6119 2511

Email
mbage46@gmail.com

Person responsible for scientific 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

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Street address
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City
Tehran

Province
Tehran

Postal code
1419733141

Phone
+98 21 6119 2511

Email
mbage46@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Nikoo Sadat Naghibi

Position
resident

Latest degree
Medical doctor

Other areas of specialty/work
Anesthesiology

Street address
Unit 201, Flat 2,No 3, Dead End Rahnamon, Elahiye

City
Tehran

Province
Tehran

Postal code
6155856681

Phone
+98 21 8163 3698

Email
nikoonaghibi@gmail.com

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