

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of endotracheal epinephrine effect on Increasing Oxygen Saturation level in COVID-19 patients with severe pulmonary involvement

Protocol summary

Study aim

Improved oxygenation of patients with severe COVID-19

Design

The study was designed as a single-blind clinical trial. The study population will be patients undergoing ventilation in the ICU with positive PCR for coronavirus. The sample size was calculated in each group of 15 people. Assigning samples to two groups will also be simple random.

Settings and conduct

Patients are divided into two groups based on simple random distribution. The first group is given 3 ml of adrenaline (one in 1000) plus 2 ml of normal saline. The second group is given 5 ml of normal saline. Patients under ventilation in the ICU of Ayatollah Mousavi Hospital in Zanjan, Iran will enroll in this study

Participants/Inclusion and exclusion criteria

Inclusion criteria: age over 18 y; PCR positive for COVID-19; Dyspnea, cough, and fever at the time of admission; under invasive mechanical ventilation; Pulmonary involvement in lung imaging. Exclusion criteria: history of cardiovascular diseases; history of brain diseases; history of pulmonary diseases; pregnancy

Intervention groups

3 cc of adrenaline (1 in 1000) plus 2 cc of normal saline is prescribed for case group.

Main outcome variables

Oxygen saturation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210613051560N1**

Registration date: **2021-12-20, 1400/09/29**

Registration timing: **prospective**

Last update: **2021-12-20, 1400/09/29**

Update count: **0**

Registration date

2021-12-20, 1400/09/29

Registrant information

Name

Masoud Asadi-Khiavi

Name of organization / entity

Country

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masadi@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-22, 1400/10/01

Expected recruitment end date

2022-04-21, 1401/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of endotracheal epinephrine effect on Increasing Oxygen Saturation level in COVID-19 patients with severe pulmonary involvement

Public title

Endotracheal epinephrine effect on COVID-19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

PCR positive for COVID-19 Tachypnea, cough and fever at the time of admission Under aggressive mechanical ventilation Pulmonary involvement in lung imaging

Exclusion criteria:

History of cardiovascular diseases History of brain diseases History of pulmonary diseases Pregnancy

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization will perform on eligible patients using intratracheal epinephrine or intratracheal normal saline in every other manner. From the beginning, it is agreed to assign individual numbers to the intervention group and even numbers to the control group. Then extract the random sample size from the table of random numbers and assign each number (odd number to the first patient and even number to the second patient) to each patient. In other words, the first patient to qualify for the study will enroll in the intervention group and be treated using intratracheal epinephrine, and the second patient to qualify will enroll in the control group and be treated using intratracheal normal saline. That is, randomization is done by marking the even and odd numbers assigned to each case and is not considered as a sequential (non-random) style. This process will continue until the groups are completed.

Blinding (investigator's opinion)

Single blinded

Blinding description

Patients are unaware of the type of intervention.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Zanjan University of Medical Sciences

Street address

Zanjan University of Medical Sciences, Dr.Sobouti

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Province

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Postal code

4513956184

Approval date

2021-10-27, 1400/08/05

Ethics committee reference number

IR.ZUMS.REC.1400.342

Health conditions studied

1

Description of health condition studied

COVID-19

ICD-10 code

J12.81

ICD-10 code description

Pneumonia due to SARS-associated coronavirus

Primary outcomes

1

Description

Oxygen saturation

Timepoint

Oxygen saturation is measured before intervention and 5, 10, 30 and 60 minutes after intervention.

Method of measurement

Using pulse oximetry and ABG

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients with severe COVID-19 under mechanical ventilation who receive intratracheal epinephrine. At the beginning of enrollment of patients in this group, for each patient in this group, 3 ml of adrenaline one in 1000 (manufactured by Iran Hormone Pharmaceutical Company) plus 2 ml of normal saline 0.9% (manufactured by Shahid Ghazi Pharmaceutical Company) is prescribed in a nebulized form. And the consequences mentioned in the presented plan are measured in the relevant schedule.

Category

Treatment - Drugs

2

Description

Control group: Patients with severe Covid-19 who receive intratracheal normal saline.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Mousavi Hospital, Zanjan

Full name of responsible person

Taraneh Naghibi

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Zanjan University of Medical Sciences

Full name of responsible person

Alireza Shoghli

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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

Zanjan 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**

Zanjan University of Medical Sciences

Full name of responsible person

Taraneh Naghibi

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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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

Yes - There is 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

paper publication

When the data will become available and for how long

next one years

To whom data/document is available

all researchers

Under which criteria data/document could be used

research use

From where data/document is obtainable

Taraneh Naghibi

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

By sending an email

Comments