

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

Prone position effectiveness in Non invasive ventilation of covid-19 patients undergoing respiratory failure

Protocol summary

Study aim

Determining the effect of prone position in patients with covid 19 with respiratory failure treated with non-invasive ventilation methods

Design

Patients with acute respiratory failure who, despite BiPAP treatment, still have low saturation and a pao₂ to FIO₂ ratio of less than 300 who are admitted to the intensive care unit during the study period.

Settings and conduct

Patients with acute respiratory failure whose oxygenation does not rise with BiPAP and other non invasive ventilation method, are placed on their chests and their levels of saturation and blood gases are measured.

Participants/Inclusion and exclusion criteria

Coronary patients with acute respiratory failure hospitalized in the intensive care unit with a desire to cooperate

Intervention groups

In patients with acute respiratory failure who have not responded to treatment with non-invasive ventilation and still have low oxygen. The patient is asked to lie on his stomach, after which the patient's oxygenation and pao₂ improvement will be measured.

Main outcome variables

Oxygenation of patients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150107020592N25**

Registration date: **2020-06-13, 1399/03/24**

Registration timing: **retrospective**

Last update: **2020-06-13, 1399/03/24**

Update count: **0**

Registration date

2020-06-13, 1399/03/24

Registrant information

Name

Seyed Mohammad Reza Hashemian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2610 9944

Email address

iran.criticalcare@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-20, 1399/01/01

Expected recruitment end date

2020-05-20, 1399/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Prone position effectiveness in Non invasive ventilation of covid-19 patients undergoing respiratory failure

Public title

Prone position effectiveness in Non invasive ventilation of covid-19 patients undergoing respiratory failure

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Positive covid patients Patients hospitalized in the intensive care unit Patients with acute respiratory failure

Exclusion criteria:

Patients with increased cerebral pressure Patients with increased ocular pressure

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Masih Daneshvari Hospital the Educational ,
Research and Treatment center.

Street address

Masih Daneshvari Hospital, Darabad Avenue, Shahid
Bahonar roundabout, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1956944413

Approval date

2020-03-10, 1398/12/20

Ethics committee reference number

IR.SBMU.NRITLD.REC.1399.009

Health conditions studied**1****Description of health condition studied**

covid-19

ICD-10 code

U07.1

ICD-10 code description

COVID-19 Disease

Primary outcomes**1****Description**

Oxygenation

Timepoint

Up to four days after pron position

Method of measurement

pulse Oximetry

Secondary outcomes

empty

Intervention groups**1****Description**

Patients with acute respiratory failure who are being treated for non-invasive ventilation will be put into a prone position, and their saturation and respiratory gas will be measured within four days.

Category

Treatment - Other

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

Masih Daneshvari Hospital

Full name of responsible person

Seyyed Mohammadreza Hashemian

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

dr.seyyad mohammadreza hashemian

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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
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Seyed Mohammad Reza Hashemian
Position
Professor
Latest degree
Subspecialist
Other areas of specialty/work
Anesthesiology
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Person responsible for updating data

Contact

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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

Yes - There is a plan to make this available

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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All patient information can be published after deleting the name

When the data will become available and for how long

It will take a month from the time of application

To whom data/document is available

All professors of medical universities in the country

Under which criteria data/document could be used

If the professors present their proposal and letter from their university by sending a message to Dr.

Hashemian's e-mail, they will send their e-mail request and the names and numbers of the patients will be deleted and their questionnaires, data and analysis will be sent to their e-mails.

From where data/document is obtainable

professor hashemian in masih daneshvari hospital

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

one month

Comments