Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

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

Protocol summary

Study aim
Determining the effect of perone 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 Edjucational , 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

Street address
Masih Daneshvari Hospital, Darabad, Niavaran Sq, Tehran, Iran

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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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End of niavaran,Darabad

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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 scientific inquiries

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Person responsible for updating data

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198396-3113
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Web page address

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