

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Aug 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

Street address

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

City

Tehran

Province

Tehran

Postal code

1956944413

Phone

+98 21 2712 2265

Email

iran.criticalcare@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

dr.seyyad mohammadreza hashemian

Street address

End of niavaran,Darabad

City

Tehran
Province
Tehran
Postal code
1956944413
Phone
+98 21 2610 9512
Email
iran.criticalcare@yahoo.com
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
Street address
Masih Daneshvari Hospital, Darabad, Niavaran Street,
Tehran, Iran
City
Tehran
Province
Tehran
Postal code
198396-3113
Phone
+98 912 111 9279
Fax
Email
smrhashemian@sbmu.ac.ir
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences
Full name of responsible person
Seyed Mohammad Reza Hashemian
Position
Professor
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Province
Tehran
Postal code
198396-3113
Phone
+98 912 111 9279
Fax
Email
smrhashemian@sbmu.ac.ir
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Seyed Mohammad reza hashemian
Position
professor
Latest degree
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Other areas of specialty/work
Anesthesiology
Street address
Masih Daneshvari Hospital, Darabad, Niavaran Sq,
Tehran, Iran
City
Tehran
Province
Tehran
Postal code
198396-3113
Phone
+98 21 2610 9512
Fax
Email
smrhashemian@sbmu.ac.ir
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