Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of prone and supine position on oxygenation of patients with COVID-19 with acute hypoxemia treated using reservoir mask

Protocol summary

Study aim
Control of pulmonary involvement in the initial stages of COVID-19 and before reaching severe degrees of ARDS

Design
The randomized, controlled clinical trial, phase 3, will be conducted on 30 hospitalized patients with SARS with acute hypoxia. For randomization, at first stage, 30 spheres from one to 30 are considered and following that will be randomly divided into two equal parts, including P (prone) and group S (supine), and then the ball of each group are taken out and the intended sequence will be recorded

Settings and conduct
Eligible patients admitted to COVID-19 ward at Kosar hospital, Semnan are assessed after being in the position of peron and supine and returne to normal position. After three days of receiving the oxygen by reserve bag, ABG, ESR, CRP, PaO2 and FiO2 are checked and compared in the two groups.

Participants/Inclusion and exclusion criteria
30 patients with acute hypoxia and hospitalized for SARS-CoV-2. Inclusion criterion included patients admitted to the ward with SARS-CoV-2 whose diagnosis was confirmed by PCR test and acute hypoxemia based on PaO2/FiO2 between 150-300 and age between 18 and 70 years old. Exclusion criterion included respiratory arrest or unstable cardiorespiratory condition, inability to protect the airways, apnea, intolerance of prone position. facial and oral trauma at the last 2 weeks, pulmonary embolism in the last two years, pregnancy and systemic diseases including asthma, chronic obstructive pulmonary disease, heart failure, unstable angina pectoris exclude from study.

Intervention groups
In intervention group, patients who need to continuous oxygen therapy by reserve bag will be placed in a prone position for one hour, every three hours up to three days. In control group, patients who need to continuous oxygen therapy by reserve bag will be placed in a supine position .

Main outcome variables
Arterial blood oxygen saturation level

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20151020024625N12**
Registration date: **2021-04-30, 1400/02/10**
Registration timing: **registered_while_recruiting**

Last update: **2021-04-30, 1400/02/10**
Update count: **0**

Registration date
2021-04-30, 1400/02/10

Registrant information

Name
Mehrdad Zahmatkesh

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 23 3343 7844

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mehrdadzahmatkesh@semums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-04-21, 1400/02/01

Expected recruitment end date
2021-06-21, 1400/03/31

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of prone and supine position on oxygenation of patients with COVID-19 with acute hypoxemia treated using reservoir mask

Public title

Assessing of prone and supine position on oxygenation of patients with COVID-19

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Confirmed COVID-19 based on PCR test PaO2/FiO2 ratio between 150-300

Exclusion criteria:

Patient's intolerance of prone position Facial and oral trauma during the last 2 weeks Asthma and chronic obstructive pulmonary disease, Heart failure Unstable angina pectoris

Age

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

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

For randomization, at first stage, 30 spheres from one to 30 are considered and following that was randomly divided into two equal parts, including P (prone) and group S (supine), and then using a lottery container, the ball of each group was taken out and the intended sequence was recorded.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ŝemnan University of Medical Sciences

Street address

Central office of Semnan University of Medical Sciences, Basidj Boulevard

City

Semnan

Province

Semnan

Postal code

3514799442

Approval date

2020-09-22, 1399/07/01

Ethics committee reference number

IR.SEMUMS.REC. 1399.201

Health conditions studied

1

Description of health condition studied

Acute respiratory distress syndrome

ICD-10 code

R06.03

ICD-10 code description

Acute respiratory distress syndrome

Primary outcomes

1

Description

Improving arterial blood oxygenation

Timepoint

Every three hours up to three days

Method of measurement

Pulse Oximeter Blood Oxygen Saturation

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients who need to continuous oxygen therapy by reserve bag will be placed in a prone position for one hour, every three hours up to three days.

Category

Treatment - Other

2

Description

Control group: Patients who need to continuous oxygen therapy by reserve bag will be placed in a supine position .

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Kowsar Hospital
Full name of responsible person
Mohammad Bahrami
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Semnan 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
Semnan University of Medical Sciences
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Position
Researchman
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Yes - There is a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be 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
Anonymised data will be offered.
When the data will become available and for how long
After publishing of final report
To whom data/document is available
Researcher who working in academic institutions
Under which criteria data/document could be used
Referees and competent people
From where data/document is obtainable
Contact with scientific responsible
What processes are involved for a request to access data/document
After verifying the applicant's position
Comments