

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 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)

Phone

+98 23 3343 7844

Email address

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 Semnan 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

Street address

Amin Avenue, Basidj Boulevard

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351989995

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+98 23 3142 2120

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bahramimohammad.k@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Parviz Kokhaei MD

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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

Full name of responsible person

Mehrdad Zahmatkesh

Position

Researchman

Latest degree

Bachelor

Other areas of specialty/work

Epidemiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Mahboubeh Darban MD

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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Person responsible for updating data

Contact

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Mehrdad Zahmatkesh

Position

Researchmen

Latest degree

Bachelor

Other areas of specialty/work

Epidemiology

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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