Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Nov 2026

Effectiveness of prone positioning combined with active cycle of breathing techniques in non intubated COVID-19 patients at Hayatabad Medical Complex, Peshawar.

Protocol summary

Study aim

Literature has reported beneficial effects of prone positioning but in our region the use of this positioning is dependent on patients' will. Currently to the investigator's knowledge, no such trial has been documented comparing prone positioning and prone positioning combined with ACBTs, studies only showed that prone positioning is feasible and effective for COVID-19 patients. so the aim of this study is to determine the effectiveness of prone positioning combined with ACBT techniques in non-intubated COVID-19 patients at HAYATABAD MEDICAL COMPLEX, PESHAWAR.

Design

Randomized controlled trial

Settings and conduct

The data will be collected from 97 patients admitted in Hayatabad Medical complex Peshawar. Participants and assessor will be blinded

Participants/Inclusion and exclusion criteria

Inclusion Criteria: i. Admitted patients ii. Laboratory confirmed SARS-COV-2 having PCR or pharyngeal swab positive. iii. Both male and female gender. iv. Age ≥18 years. v. Noninvasive ventilation Exclusion Criteria: i. Intubated patients ii. Pregnancy iii. Patient inability to tolerate prone positioning iv. Hemodynamically unstable (SBP<90mmhg) or arrhythmias v. Pressure sores vi. Seizures vii. Recent abdominal surgery1)

Intervention groups

This control group will comprise of prone positioning for 1 hour session, five sessions per day each spaced 2 hours for 1 week. The interventional group will be same as control group but with addition of ACBT technique. The technique comprises breathing Control in which patient will breathe in and out gently through nose then deep Breath through nose hold for 2-3 sec before breath out 3-5 times then huffing or Forced Expiratory Technique to remove secretions for 15-20 minutes for 1 week

Main outcome variables

1. heart rate 2. respiratory rate 3 blood pressure 4 oxygen saturation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211103052957N1**
Registration date: **2021-11-10, 1400/08/19**
Registration timing: **prospective**

Last update: **2021-11-10, 1400/08/19**
Update count: **0**

Registration date

2021-11-10, 1400/08/19

Registrant information

Name

Zainab Jahan

Name of organization / entity

Hayatabad Medical complex Peshawar Pakistan

Country

Pakistan

Phone

+92 91 9217140

Email address

zaib1012@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-18, 1400/08/27

Expected recruitment end date

2022-01-18, 1400/10/28

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effectiveness of prone positioning combined with active cycle of breathing techniques in non intubated COVID-19 patients at Hayatabad Medical Complex, Peshawar.

Public title
Effectiveness of prone positioning combined with active cycle of breathing techniques in non intubated COVID-19 patients at Hayatabad Medical Complex, Peshawar.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Admitted patients Laboratory confirmed SARS-COV-2 having PCR or pharyngeal swab positive Both male and female gender Age ≥18 years. Noninvasive ventilation
Exclusion criteria:
Intubated patients Pregnancy Patient inability to tolerate prone positioning Hemodynamically unstable (SBP<90mmhg) or arrhythmias Pressure sores Seizures Recent abdominal surgery
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **97**
Randomization (investigator's opinion)
Randomized
Randomization description
After participants are selected, they will be randomly allocated to control group and experimental group using lottery method in which they will asked to select a piece of paper from a box. The piece of paper will be marked with initial of the groups (such as A or B) and then the participants will be allocated to the group initial that was on paper
Blinding (investigator's opinion)
Double blinded
Blinding description
Due to nature of study, it will not be feasible to blind researcher/therapist. However, assessor, who will assess pre and post measurements, will be blinded.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Hospital research and ethical committee (IRED)
Street address
Phase 4 Hayatabad Peshawar
City
Peshawar
Postal code
25000
Approval date
2021-09-09, 1400/06/18
Ethics committee reference number
526/HEC/B&PSC/2021

Health conditions studied

1

Description of health condition studied
COVID-19
ICD-10 code
U07.1
ICD-10 code description
U07. 1 COVID-19, virus identified

Primary outcomes

1

Description
Oxygen saturation
Timepoint
Outcomes will be measure after each treatment session for 7 consecutive days.
Method of measurement
The outcomes will be measured by using pulse oximeter and cardiac monitor

2

Description
Respiratory rate
Timepoint
Outcomes will be measure after each treatment session for 7 consecutive days.
Method of measurement
The outcomes will be measured by using pulse oximeter and cardiac monitor

3

Description
Heart rate
Timepoint

Outcomes will be measure after each treatment session for 7 consecutive days.

Method of measurement

The outcomes will be measured by using pulse oximeter and cardiac monitor

4

Description

Blood pressure

Timepoint

Outcomes will be measure after each treatment session for 7 consecutive days.

Method of measurement

The outcomes will be measured by using pulse oximeter and cardiac monitor

Secondary outcomes

empty

Intervention groups

1

Description

Control group: prone positioning for 1 hour after every 2 hours 5 times a day for 7 days

Category

Treatment - Other

2

Description

Intervention group: prone positioning with ACBT for 1 hour after every 2 hours 5 times a day for 7 days

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Hayatabad Medical complex

Full name of responsible person

Professor Dr . Wajid Ali Akhunzada

Street address

Phase 4 Hayatabad Peshawar

City

Peshawar

Postal code

25000

Phone

+92 91 9217140

Email

info@hmckp.gov.pk

Web page address

https://www.hmckp.gov.pk/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Khyber Medical University, Peshawar, Pakistan.

Full name of responsible person

Dr. Mujeeb Ur Rehman

Street address

Phase 4 Hayatabad Peshawar

City

Peshawar

Postal code

25000

Phone

+92 91 9217703

Fax

+92 91 9217704

Email

info@kmu.edu.pk

Web page address

https://www.kmu.edu.pk/

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Khyber Medical University, Peshawar, Pakistan.

Proportion provided by this source

1

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

Khyber Medical University

Full name of responsible person

Zainab Jahan

Position

Student

Latest degree

Medical doctor

Other areas of specialty/work

Physiotherapy

Street address

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+92 91 5254545

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zaib1012@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Khyber Medical University

Full name of responsible person
Zainab Jahan

Position
student

Latest degree
Medical doctor

Other areas of specialty/work
Physiotherapy

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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
the data regarding outcome measures and demographics will be shared

When the data will become available and for how long
the data will be available after the completion of study.

To whom data/document is available
people in academic institutes and working in clinical setups will be able to access this data

Under which criteria data/document could be used
the data could be used for experimental analysis by clinicians or academicians.

From where data/document is obtainable
the data can be obtained from principal author through email address zaib1012@gmail.com

What processes are involved for a request to access data/document
the applicants will email to the author who will respond them asap.

Comments