अखिल भारतीय आयुर्विज्ञान संस्थान, जोधपुर
All India Institute of Medical Sciences, Jodhpur
संस्थागत नैतिकता समिति
Institutional Ethics Committee

No. AIIMS/IEC/2020/ 3021 **Date: 01/06/2020**

ETHICAL CLEARANCE CERTIFICATE

Certificate Reference Number: **AIIMS/IEC/2020-21/**2040

Project title: **"Effectiveness of Awake Self Proning strategy in COVID-19: An open-labelled randomized controlled trial"**

Nature of Project:	**Research Project Submitted for Expedited Review**
Submitted as:	**Other**
Principal Investigator:	**Dr. Maya Gopalakrishnan**
Co-Investigators:	**Dr. Deepak Kumar, Dr. M.K.Garg, Dr. Nishant Chauhan, Dr. Gopal Krishna Bohra, Dr. Suman Saurabh, Dr. Pradeep Bhatia, Dr. Vijaya Lakshmi Nag & Dr. Praveen Sharma**

Institutional Ethics Committee after thorough consideration accorded its approval on above project.

The investigator may therefore commence the research from the date of this certificate, using the reference number indicated above.

Please note that the AIIMS IEC must be informed immediately of:

- Any material change in the conditions or undertakings mentioned in the document.
- Any material breaches of ethical undertakings or events that impact upon the ethical conduct of the research.
- In case of any issue related to compensation, the responsibility lies with the Investigator and Co-Investigators.

The Principal Investigator must report to the AIIMS IEC in the prescribed format, where applicable, bi-annually, and at the end of the project, in respect of ethical compliance.

AIIMS IEC retains the right to withdraw or amend this if:

- Any unethical principle or practices are revealed or suspected
- Relevant information has been withheld or misrepresented

AIIMS IEC shall have an access to any information or data at any time during the course or after completion of the project.

Please Note that this approval will be rectified whenever it is possible to hold a meeting in person of the Institutional Ethics Committee. It is possible that the PI may be asked to give more clarifications or the Institutional Ethics Committee may withhold the project. The Institutional Ethics Committee is adopting this procedure due to COVID-19 (Corona Virus) situation.

If the Institutional Ethics Committee does not get back to you, this means your project has been cleared by the IEC.

On behalf of Ethics Committee, I wish you success in your research.

Dr. Praveen Sharma
Member secretary
Institutional Ethics Committee
AIIMS,Jodhpur

Clinical Trial Details (PDF Generation Date :- Mon, 17 Aug 2020 08:37:46 GMT)

CTRI Number	CTRI/2020/06/025804 [Registered on: 11/06/2020] - **Trial Registered Prospectively**
Last Modified On	11/06/2020
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Process of Care Changes
Study Design	Randomized, Crossover Trial
Public Title of Study	Effectiveness of lying face down in improving the outcome of COVID-19 patients
Scientific Title of Study	Effectiveness of awake self proning strategy in COVID-19: An open-labelled randomized controlled trial

Secondary IDs if Any

Secondary ID	Identifier
NIL	NIL

Details of Principal Investigator or overall Trial Coordinator (multi-center study)

Details of Principal Investigator	
Name	Dr Maya Gopalakrishnan
Designation	Assistant Professor, Department of Medicine
Affiliation	All India Institute of Medical Sciences- Jodhpur
Address	Room 41, B-block, OPD Ground floor, AIIMS_Jodhpur, MIA Phase 2, Basni Jodhpur RAJASTHAN 342005 India
Phone	9994492075
Fax	
Email	maya.gopalakrishnan@gmail.com

Details Contact Person (Scientific Query)

Details Contact Person (Scientific Query)	
Name	Dr Maya Gopalakrishnan
Designation	Assistant Professor, Department of Medicine
Affiliation	All India Institute of Medical Sciences- Jodhpur
Address	Room 41, B block, OPD ground floor, AIIMS_Jodhpur, MIA Phase 2, Basni Jodhpur RAJASTHAN 342005 India
Phone	9994492075
Fax	
Email	maya.gopalakrishnan@gmail.com

Details Contact Person (Public Query)

Details Contact Person (Public Query)	
Name	Dr Maya Gopalakrishnan
Designation	Assistant Professor, Department of Medicine
Affiliation	All India Institute of Medical Sciences- Jodhpur
Address	Room 41, B block, OPD ground floor, AIIMS_Jodhpur, MIA Phase 2, Basni Jodhpur RAJASTHAN 342005 India
Phone	9994492075

Fax	
Email	maya.gopalakrishnan@gmail.com

Source of Monetary or Material Support

Source of Monetary or Material Support
> Research Section, Room C-116, 1st floor, Academic Main Building, AIIMS- Jodhpur, MIA Phase 2, Basni, Rajasthan, Jodhpur, India

Primary Sponsor

Primary Sponsor Details	
Name	AIIMS Jodhpur
Address	MIA Phase 2, Basni, Jodhpur, Rajasthan, 342005
Type of Sponsor	Government medical college

Details of Secondary Sponsor

Name	Address
NIL	NIL

Countries of Recruitment

List of Countries
India

Sites of Study

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
Dr Maya Gopalakrishnan	AIIMS Jodhpur	Ward no. 5A-5D and 6A-6D, COVID-19 treatment zone, 5th and 6th floor, Inpatient Department (IPD) block, AIIMS Jodhpur, MIA Phase 2, Basni Jodhpur RAJASTHAN	9994492075 maya.goapalkrishnan@gmail.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Institutional Ethics Committee - AIIMS Jodhpur	Approved	01/06/2020	No

Regulatory Clearance Status from DCGI

Status	Date
Not Applicable	No Date Specified

Health Condition / Problems Studied

Health Type	Condition
Patients	Coronavirus as the cause of diseases classified elsewhere

Intervention / Comparator Agent

Type	Name	Details
Intervention	Awake self proning strategy	The COVID-19 patient will be asked to be in prone position and its effect on improvement of their blood oxygenation will be seen using a finger saturation probe.
Comparator Agent	Lying supine or sitting	The COVID-19 patient will be lying supine or sitting and its effect on improvement of blood oxygenation will be seen using a finger saturation probe.

Inclusion Criteria

Inclusion Criteria	
Age From	18.00 Year(s)
Age To	99.00 Year(s)
Gender	Both
Details	1. >18 years of age

	2. Diagnosed as COVID-19 positive by RT- PCR 3. Oxygen saturation 4. Can communicate and self-prone

Exclusion Criteria

Exclusion Criteria	
Details	1. Any patient requiring immediate intubation and ventilatory care 2. Hemodynamic instability BP3. Elevated intracranial pressure 4. Altered sensorium or history of seizures 5. Any psychiatric comorbidity 6. Massive hemoptysis in the last 48 hours (>500 ml or requiring transfusion) 7. Morbid obesity where self-proning is not feasible 8. Pregnancy 9. Patients at high risk of requiring CPR or defibrillation (Known arrhythmias)

Method of Generating Random Sequence	Computer generated randomization
Method of Concealment	Centralized
Blinding/Masking	Open Label

Primary Outcome

Outcome	Timepoints
Primary outcomes (Phase 1 study): 1. Oxygen saturation measured using by pulse oximeter at 0, 10, 20, 30, 40 minutes Primary Outcomes (Phase 2 study): 1. Need for endotracheal intubation and mechanical ventilation measured at discharge or death 2. Mortality up to 30 days after enrolment	Primary outcomes (Phase 1 study): 1. Oxygen saturation measured using by pulse oximeter at 0, 10, 20, 30, 40 minutes Primary Outcomes (Phase 2 study): 1. Need for endotracheal intubation and mechanical ventilation measured at discharge or death 2. Mortality up to 30 days after enrolment

Secondary Outcome

Outcome	Timepoints
For phase 2 study: Phase 2 study: 1. Time to endotracheal intubation/ventilation measured using hospital record at discharge. 2. Duration of requirement of oxygen support measured using clinical proforma at patient discharge 3. Duration of hospital stay measured using using hospital record at discharge	Secondary outcome will be measured at patients at patients discharge or death.

Target Sample Size	**Total Sample Size=**120 **Sample Size from India=**120 **Final Enrollment numbers achieved (Total)=**Applicable only for Completed/Terminated trials **Final Enrollment numbers achieved (India)=**Applicable only for Completed/Terminated trials
Phase of Trial	N/A
Date of First Enrollment (India)	20/06/2020
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**0 **Months=**4 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Not Yet Recruiting
Publication Details	NIL
Brief Summary	**Background and study aims:**

COVID-19 is a condition caused by the coronavirus (called SARS-CoV-2) that was first identified in late 2019. This virus can infect the respiratory (breathing) system. Some people do not have symptoms but can carry the virus and pass it on to others. People who have developed the condition may develop a fever and/or a continuous cough among other symptoms. This can develop into pneumonia. Pneumonia is a chest infection where the small air pockets of the lungs, called alveoli, fill with liquid and make it more difficult to breathe.

In 2020, the virus has spread to many countries around the world and neither a vaccine against the virus or specific treatment for COVID-19 has yet been developed. As of March 2020, it is advised that people minimize travel and social contact, and regularly wash their hands to reduce the spread of the virus.

Groups who are at a higher risk from infection with the virus, and therefore of developing COVID -19, include people aged over 70 years, people who have long-term health conditions (such as asthma or diabetes), people who have a weakened immune system and people who are pregnant . People in these groups, and people who might come into contact with them, can reduce this risk by following the up-to-date advice to reduce the spread of the virus.

Objective of the study

The trial will be done to see whether putting COVID-19 patients on prone position (lying on their belly) improves their oxygenation of blood and their clinical outcome.

Who can participate?

Adult patients diagnosed with COVID-19.

What does the study involve?

It will have two phases - first phase will be to see whether putting COVID-19 patients on prone position improves their oxygen level as measured by their finger probe. The patients will be assigned to one of the two groups. The first group will remain prone (on their belly) for 10 minutes, will lie

sideways on their left for 10 minutes ,will lie sideways on their right for 10 minutes and will supine (on their back) for 10 minutes. At the end of each phase, oxygen saturation will be measured. Patients in the second group will go through the same steps in reverse order.

If the first phase of the study shows promise, phase 2 of the study will be initiated. New COVID-19 patients will be assigned to one of the two groups - intervention and control arm. The patients assigned to intervention group will undergo the prone, lying on left side, lying on right side and supine cycle with each position for 30 minutes i.e total duration of 2 hours. 3 such cycles will be repeated in the day.

The control group patients will receive usual care and will stay in

whichever position they are comfortable with.

The effect of the intervention on requirement of intubation (for ventilatory support) and mortality among patients will be seen as compared to the control group.

What are the possible benefits and risks of participating?

There are no risks for participating. Any position deemed uncomfortable and reducing the saturation to unsafe levels will be discontinued immediately.

Where is the study run from?

All India Institute of Medical Sciences - Jodhpur, India

When is the study starting and how long is it expected to run for?

The trial is expected to start enrolling in June 2020 and will last till October 2020.

Who is funding the study ?

All India Institute of Medical Sciences - Jodhpur, India

Who is the main contact?

Dr Maya Gopalakrishnan, Assistant Professor, Department of Medicine, email: maya.gopalakrishnan@gmail.com, Mobile: 9994492075