

Novel Clinical Trial Design for the Study of the Effect of Prone Position on Clinical Outcomes of COVID-19 Patients

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Dear Editor

COVID-19 pulmonary involvement leads to complications such as pneumonia and Acute Respiratory Distress Syndrome (ARDS) (1). Several studies have demonstrated that prone positioning can improve oxygenation in patients with ARDS or Severe Acute Respiratory Syndrome (SARS) (2-4). An intense respiratory effort among moderate and severe ARDS patients during spontaneous ventilation can intensify lung injury (5).

According to new research findings, prone positioning in ARDS patients can decrease mortality (6-9). In ARDS patients, prone positioning provides a more homogeneous supply of the inspired gas and a better matching between ventilation and perfusion, thereby improving oxygen saturation (SpO₂)(2). This is facilitated by lung inflation, increased lung volumes (for example, increased residual and end-expiratory volume), improved pulmonary perfusion and gas exchange, and reduced pulmonary arterial pressure. In addition, the prone position leads to lung protection and hemodynamic maintenance, as it distributes the pressure in the lungs by reducing the steep trans-pulmonary pressure gradient across its vertical axis and facilitates a more homogeneous distribution of the pulmonary stress and strain. Finally, it reduces the pressure on the right ventricle (2, 3).

A multicenter, prospective, controlled trial showed that the prone position increased ventilator-free days, decreased extubation time, and reduced mortality in patients with ARDS (10). Moreover, there is evidence suggesting that the experiential use of prone positioning in patients with COVID-19 can improve oxygenation. This intervention and other similar interventions can be used in patients with COVID-19 (11). A case study confirmed this in a pregnant woman with severe COVID-19 infection supported by mechanical ventilation. As the SpO₂ did not improve, her body was laid between the supine and prone positions. Consequently, there were significant improvements in her SpO₂ and clinical and para-clinical tests. Moreover, ultrasonography of the fetus demonstrated normal fetal development and the absence of any discernible abnormality (9). Pan et al. showed that alternating body positions between supine and prone led to improved lung recruitment in patients with COVID-19 who had established ARDS(8).

The lack of definitive treatment for this vicious disease has led to increased efforts by healthcare providers, especially nurses, to develop supportive and palliative care strategies. However, the novelty of the disease and the shortage of evidence-based studies have led to uncertainty among healthcare providers, hindering them in deciding on a suitable

intervention. Consequently, it may be proposed that the prone positioning may be clinically beneficial. Regarding the outcomes, this intervention can be used as an effective strategy for patients with COVID-19 as it is cost-effective and needs no special equipment.

Therefore, the present clinical trial has been approved by the ethics committee of the Lorestan University of Medical Sciences with the ethics code IR.LUMS.REC.1399.059, and the clinical trial registration code of IRCT20160126026217N4, with the title "Investigation of Prone Positioning on Clinical Outcomes of COVID-19 Patients". It is one of the first trials designed to evaluate the clinical effects of prone positioning in patients with COVID-19. The study population included 82 patients with COVID-19 who were admitted to the hospital's general wards and were randomly assigned to the intervention and control groups. The diagnosis of COVID-19 was based on clinical symptoms and signs, PCR tests, and chest CT scan findings compatible with the COVID-19 pneumonia pattern. The inclusion criteria comprised an age range of 35-70 years, lack of need for supportive ventilation, lack of COPD or asthma, lack of orthopedic and spine disorders, and no history of thoracic surgery during the last six months. Exclusion criteria included inability to tolerate prone position, severe cough, nausea and vomiting during positioning, sudden changes in vital signs to a level greater than 20% of the baseline, and unwillingness to continue participating. The patients in the intervention group were alternately positioned in the prone position for 8 hours per day, while the patients in the control group had the usual positioning. The participants were assessed for SpO₂, respiratory rate, dyspnea severity score, mean arterial pressure, pulse rate, hospital stay, intensive care unit admission, and mortality. The authors expect to complete the study in the next few months. We hope this trial will provide valuable information on the potential effects of prone positioning on alleviating symptoms in patients with COVID-19.

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