

# INPLASY PROTOCOL

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**Conflicts of interest:**  
No conflicts of interest to declare.

## Prone position in mechanically ventilated patients with acute respiratory: a scoping review protocol of adverse events published from PROSEVA study

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**Review question / Objective:** The following research question was structured based on the population, concept and context (PCC) method according to Arksey H. and O'Malley methodology: Which adverse events associated with prone position (PP) in mechanically ventilated adult patients with acute respiratory failure (ARF) have been reported in the scientific literature from 2013? The primary objective will be to identify adverse events associated with PP in mechanically ventilated adult patients with ARF described in documents published from 2013. The secondary objective will be to identify the therapeutic approach associated to PP adverse events.

**Condition being studied:** The PP continues to be widely used due to effectiveness in the ARF management, particularly after PROSEVA study. Further, PP recommendations have been emphasized during the COVID-19 pandemic, which may promote a greater presence of associated adverse events. Based on the International Classification for Patient Safety of the World Health Organization, "adverse event" was defined as any type of unforeseen incident or unexpected complication that arises as a consequence of PP and not necessarily due to the underlying disease, bringing negative consequences for the patient.

**INPLASY registration number:** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 04 December 2020 and was last updated on 04 December 2020 (registration number INPLASY2020120020).

### INTRODUCTION

**Review question / Objective:** The following research question was structured based on the population, concept and context (PCC)

method according to Arksey H. and O'Malley methodology: Which adverse events associated with prone position (PP) in mechanically ventilated adult patients with acute respiratory failure (ARF) have

been reported in the scientific literature from 2013? The primary objective will be to identify adverse events associated with PP in mechanically ventilated adult patients with ARF described in documents published from 2013. The secondary objective will be to identify the therapeutic approach associated to PP adverse events.

**Rationale:** The ARF affects more than one million patients worldwide each year, representing a high morbidity and mortality in intensive care unit (ICU). The therapeutic approach will depend on the pathophysiology, level of respiratory compromise, severity and presence of multiple organ failure. Commonly, respiratory support strategies include the use of a high-flow nasal cannula, non-invasive ventilation, invasive mechanical ventilation (IMV), extracorporeal membrane oxygenation, neuromuscular blocking agents, prone position (PP), or a combination of above. Particularly, PP is non-invasive, unexpensive and bedside strategy, which is feasibility in ICU. Mechanisms of the PP to combat ARF have been widely reported in the literature, including: (1) improving of ventilation/perfusion ratio, (2) increasing lung volume at the end of expiration, and (3) preventing ventilation-induced lung injury. Although PP is an increasingly used respiratory strategy, its implementation is not risk-free, especially in patients who requiring IMV. The literature reports accidental loss and/or obstruction of endotracheal tube, accidental loss of vascular accesses, drains and tubes, skin lesions; as some of the adverse events that this position includes. The appearance of adverse events could be modified according to certain factors, such as; the prior training of the health team, sedation and neuromuscular blockade practices, patient age, previous physical functioning, the use of a previously established and standardized protocol, and the time allocated to the prone duration. Based on our current knowledge, no reviews have been published collecting and classifying all available adverse events of PP in mechanically ventilated patients.

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## METHODS

**Search strategy:** A search for scientific documents will be performed in the following biomedical databases: PubMed (NCBI), CINAHL Plus with full text (EBSCO), SciELO, Cochrane Library, LILACS, and WorldWideScience, using a combination of free and MeSH terms: ("prone position" [MeSH] OR "prone position" OR "prone positions" OR "prone positioning" OR "pronation" OR "prone" OR "proning" OR "pronation/methods" OR "ventral decubitus") AND ("mechanical ventilation" OR "mechanically ventilated" OR "mechanical ventilator" OR "artificial, respiration" OR "artificial respiration" OR "mechanical ventilations" OR "respiration, artificial" [MeSH]) AND ("adult respiratory distress syndrome" OR "respiratory distress syndrome, adult" [MeSH] OR "respiratory distress syndrome, adult" OR "respiratory insufficiency" OR "acute respiratory failure" OR "acute respiratory distress syndrome" OR "respiratory failure" OR "lung insufficiency" OR "ARDS" OR "acute lung injury" OR "COVID-19" OR "coronavirus" [MeSH] OR "coronavirus" OR "SARS-CoV-2" OR "2019nCoV" OR "2019-nCoV").

**Participant or population:** Adult patients (older than or equal to 18 years) with acute respiratory failure, who require prone position and invasive mechanical ventilation.

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**Intervention:** Not applicable.

**Comparator:** Not applicable.

**Study designs to be included:** Primary studies and reviews available in biomedical databases will be included, as well as clinical practice guidelines, protocols and recommendations available in web sites of critical care scientific societies.

**Eligibility criteria:** The inclusion criteria were established to PCC method according to the Arksey H. and O'Malley methodology: (1) Population: Adult patients (older than or equal to 18 years) with ARF, who require PP and IMV; (2) Concept: Adverse events associated with PP and (3) Context: Documents published from June 2013 (from PROSEVA study) to the search date. We will exclude documents that consider patients in awake PP with any type of respiratory support other than IMV, documents from pediatric or neonatal population, documents from patients treated outside the ICU, documents performed in animal and/or experimental models (in vitro), conference abstracts, thesis papers, full text not available, documents written in languages other than English or Spanish and documents that do not mention adverse events related to PP in mechanically ventilated patients during ARF.

**Information sources:** For the identification of relevant studies, a document search will be developed using biomedical databases and hand search, following the 3 recommended stages by Joanna Briggs Institute (JJP-C, FG-S). First, an iterative search of scientific documents will be carried out in PubMed mixing free-text terms, booleans and MeSH terms associated with "prone position", "mechanical ventilation", "respiratory distress syndrome, adult", "respiratory failure", "adverse events" and "complications". Second, keywords and terms identified in the search strategies of systematic reviews extracted in the first search will be selected, and incorporated in a second search. This search will be carried out in the following biomedical

databases selected for relevance and accessibility: PubMed (NCBI), CINAHL Plus with full text (EBSCO), Scientific Electronic Library Online (SciELO), Cochrane Library, LILACS and WorldWideScience. Third, a hand search for documents will be developed in three formats: (1) relevant references will be selected from reviews identified in the biomedical databases described above, (2) search for documents in personal archives, and (3) clinical practice guidelines, protocols and/or recommendations published on web pages of scientific societies affiliated to the "World Federation of Intensive and Critical Care (WFICC)" available at <https://www.wficc.com/societies>, will be selected. The word search bar on each web page will be used to search documents using the free terms: "prone position", "prone positioning", "posición prono" and "posición prona". Two researchers (NA-S, JJP-C) will independently carry out the selection of scientific documents through two stages: 1) screening of titles and abstracts and 2) selection of full text according to the selection criteria. For disagreements during documents selection, a third investigator will decide (FG-S). Mendeley© v. 1.19.4 will be used for bibliographic management and administration of the reference database. The searches in the described sources will be carried out between October 26 and November 1, 2020.

**Main outcome(s):** To identify adverse events of prone position in mechanically ventilated patients.

**Data management:** When documents have been selected, a researcher (JJP-C) will extract the relevant data in a prespecified Excel® spreadsheet. The information extracted from the included documents will be: bibliometric variables (author, year of publication, country, study design, type of publication and journal), procedural aspects (presence of a protocol, positioning technique, use of splinting, prone dairy hours, frequency of position changes and total duration of PP), clinical variables (presence and duration of neuromuscular blockade agents, presence

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and duration of sedation and exposure to early mobilization during prone time); variables related to health staff (number of team members involved and previous training) and all adverse events associated with PP.

**Quality assessment / Risk of bias analysis:** Not applicable.

**Strategy of data synthesis:** The final documents selection process will be reported using the flow chart suggested by “Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) extension for Scoping Reviews Checklist”. Data collected will be synthesized in logical order according to the research question and will be reported in a descriptive way in text, tables and figures, reporting overall characteristics of the documents included, adverse events associated with PP, synthesis of the procedural aspects associated with PP and the frequency of appearance of the clinical variables related to health staff in the selected studies.

**Subgroup analysis:** Not applicable.

**Sensibility analysis:** Not applicable.

**Language:** English and Spanish only.

**Country(ies) involved:** Chile.

**Other relevant information:** This scoping review of Adverse Events of the PRONE position (AE-PRONE study) is framed in the Master in Physical Therapy and Rehabilitation Program, Universidad del Desarrollo, Santiago, Chile.

**Keywords:** “prone position”; “mechanical ventilation”; “respiratory distress syndrome”, “respiratory failure”, “adverse events”, “complications”.

**Dissemination plans:** Knowledge translation will be based on the End of Grant model according to the Canadian Institute of Health Researchers (CIHC), which includes diffusion, dissemination and application. To accomplish diffusion, the results will be published using a scientific

journal oriented to critical care and academic social networking including Twitter and ResearchGate. In addition, for the dissemination of the results, the supplementary material will include an informative pocket card with the main results of the study, as well as recommendations aimed at minimizing adverse events related to PP. For the application, a workshop will be held that will include national leaders and international experts who have used and researched the PP, in order to transmit the results of the study and establish a consensus that allows unifying clinical behaviors to avoid adverse events associated with this position.

**Contributions of each author:**

Author 1 - Juan José Pinto-Concha - Lead author, development of the main idea, methodology, writing and revision of the final protocol.

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