INFORMED CONSENT

Influence of the Lung Recruitment Potential on the Response to Two Positive End-Expiratory Pressure (PEEP) Titration Strategies in Patients With Acute Respiratory Distress Syndrome (ARDS)

NCT07603310

July 7th, 2026

INFORMED CONSENT FORM
(ANNEX 7)

PROJECT TITLE: "PEEP Titration Guided by Pulmonary Recruitability in Patients with ARDS: A Randomized Pilot Study"

Institution: Hospital Dr. Franco Ravera Zunino

Phone(s): +56940367716

Service or Department: Adult Critical Care Unit.

Invitation to Participate: You are being invited, in your capacity as guardian, caregiver, or responsible family member, to authorize the participation of the patient in your care in a clinical research study to be conducted in the Intensive Care Unit of Hospital Dr. Franco Ravera Zunino. The decision to participate is entirely voluntary. Before making a decision, it is important that you read the following information carefully and ask any questions you consider necessary.

The Study: This study aims to evaluate different approaches to adjusting mechanical ventilation in patients with severe respiratory compromise. Mechanical ventilation is a standard treatment in the Intensive Care Unit, and this study evaluates strategies already used in clinical practice, but in a systematic and comparative manner, for research purposes. The study has been designed as a pilot study, meaning an initial study that seeks to obtain information for the development of future broader investigations.

Objectives: The primary objective of the study is to compare two strategies for adjusting mechanical ventilation, specifically the level of positive end-expiratory pressure (PEEP), in order to evaluate their impact on clinical outcomes (ventilator-free days at 28 days) and respiratory physiological parameters. Additionally, the study seeks to obtain information on the safety and variability of these strategies for the design of future studies.

Procedures: If you authorize the participation of the patient in your care, respiratory measurements and examinations that are part of standard ICU management will be performed. This involves first performing a brief evaluation aimed at opening collapsed areas of the lung, and based on its result, mechanical ventilation (PEEP) will be adjusted using one of the standard clinical methods that will be compared in the study.

a) If many areas of the lung open, the patient will be randomly assigned to one of these groups:

Group 1: An esophageal balloon device will be used as the PEEP calculation method. This device is gently inserted through the mouth or nose into the esophagus to measure internal pressures.

Group 2: The best pulmonary compliance will be used as the PEEP calculation method, which is measured by decreasing PEEP in steps until the greatest compliance is found based on ventilatory parameters.

b) If few lung areas open, a predefined and validated table based on the concentration of oxygen being inhaled will be used as the PEEP calculation method.

All evaluations and procedures will be performed under continuous monitoring and by trained professional staff. Some measurements will be repeated during the first days of evolution, without modifying other aspects of standard treatment.

Risks: The risks associated with this study are similar to the inherent risks of standard management of patients on mechanical ventilation. These may include transient changes in blood pressure, oxygenation or ventilation, and in rare cases, pulmonary injuries such as pneumothorax. The use of the esophageal balloon may cause mild discomfort or local irritation, which are infrequent and will be managed by Unit staff. All procedures will be performed under strict medical supervision and can be immediately discontinued if any risk to the patient is detected.

Costs and Compensation: Participation in this study does not imply any additional cost for you or your family member. This study does not include economic compensation.

Benefits: In some cases, individualized adjustment of mechanical ventilation may have a clinical benefit, although this cannot be guaranteed. It is possible that the patient in your care may not receive a direct additional benefit beyond standard clinical management by participating in this study. However, the information obtained could contribute to improving the management of future patients with serious respiratory diseases.

Alternatives, Voluntariness and Withdrawal: If you do not wish to participate in the study, the patient in your care will continue to receive the Unit's standard treatment. Participation is completely voluntary and will have no impact on the care or clinical management received. Likewise, you or the patient in your care may withdraw authorization at any time, without need to provide explanations, and this will not affect in any way the medical care received. To do so, simply inform the Principal Investigator and complete the withdrawal section attached to this document.

Confidentiality of Information: All information obtained during the study will be treated confidentially. Data will be recorded with a code and will not include information that directly identifies the patient (e.g., name, ID number, medical record number, etc.). Only the research team will have access to the data, which will be used exclusively for scientific and academic purposes, always protecting the patient's privacy in accordance with current legislation.

Access to Research Results: The overall results of this study will be available once the data has been analyzed and the research is complete. If you request it from the Principal Investigator, you may access a summary of the overall study results through the research team. These results may be presented at scientific meetings or published in medical journals, always anonymously, without including information that identifies the patient.

Participant Rights: In case of doubt or question about my rights as a research subject, I can contact the Principal Investigator/Responsible (Klgo. Esteban Santis Ortiz) by email (esteban.santis@ogb.cl) or with the Scientific Ethics Committee of Hospital Dr. Franco Ravera Zunino (HFRZ), represented by its president EU. Manuel Ruz, at telephone 72-2338337, email: cec.hospitalregionalohiggins@gmail.com, or in person at the HFRZ Administration Module (4th floor; Av. Salvador Allende 0350, Rancagua).

Conclusion: After having read and understood the information in this document, and having been able to clarify all my doubts, I grant my free, informed and voluntary consent to participate in the project.

INFORMED CONSENT SIGNATURE

_____	_____	__/__/____

Name of guardian, caregiver or responsible family member ID: _____	Signature	Date
_____ Klgo. Esteban Santis Ortiz Principal Investigator ID: 16757800-4	_____ Signature	___/___/_____ Date
_____ Institution Director or Representative ID: _____	_____ Signature	___/___/_____ Date

WITHDRAWAL OF INFORMED CONSENT

I _____ (full name), ID _____, hereby VOLUNTARILY WITHDRAW the consent previously signed. As of today _____ (dd/mm/yyyy), my participation is hereby concluded.

I Accept _____ / I Do Not Accept _____ (check the chosen option) that the personal data held by the project research team be retained and used under strict confidentiality for research purposes.

_____ Name of guardian, caregiver or responsible family member ID: _____	_____ Signature	___/___/_____ Date
_____ Klgo. Esteban Santis Ortiz Principal Investigator ID: 16757800-4	_____ Signature	___/___/_____ Date
_____ Institution Director or Representative ID: _____	_____ Signature	___/___/_____ Date

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