

# Body Positioning and Pulmonary Aeration During Mechanical Ventilation

**NCT number:** 04176445

**Date of the document:** 04/27/2020

## **Scientific background**

Invasive mechanical ventilation (IMV), despite saving lives in intensive care unit (ICU), may result in neuromuscular damage and impairment of the respiratory system. This damage can be worsened by immobilization in bed or reduced by using protocols of body positioning.

Body positioning is associated with positive effects on respiratory system among patients requiring invasive mechanical ventilation, mainly when performed outside the bed. For example, the combination of sedestation in a chair and physical activity can improve lung aeration during IMV using endotracheal tube. Accordingly, passive orthostasis with the support of a tilt table has been incorporated into practice in order to allow body positioning of critical care patients outside the bed. When included in daily practice, this strategy, is associated with improvement of the level of consciousness of ICU patients. Moreover, when patients under IMV are placed in passive orthostasis using a tilt table, there is a transient increase in minute volume without a significant change in oxygenation. Nevertheless, the evidence regarding its safety and effectiveness in comparison with other body positioning strategies is still scarce, and the fulfillment of this evidence gap may contribute to improve mobilization outcomes of critically ill patients. Therefore, this study aimed to assess the effects of different mobilization positions on lung aeration of critically ill patients under IMV.

## **Methods**

### **Study design**

The present study was designed to be an open label, randomized, crossover, two-center, clinical trial aimed to assess the impact of different verticalization positions on lung aeration of patients hospitalized in the ICU under invasive mechanical ventilation using endotracheal tube. Patients were enrolled and followed from the medical-surgical ICUs of Ernesto Dornelles (40 beds) and Moinhos de Vento hospitals (17 beds), both tertiary, academic, and private hospitals, in Southern Brazil.

**Sitting position protocol:** Participants were passively placed in bedside sedestation, where they remained for 30 minutes, with back support; their hips and knees were flexed at 90° and feet supported. This position aimed at simulating sitting in a chair.

**Passive orthostasis protocol:** Participants were transferred to a tilt table (0° inclination). Safety straps were placed on the knees, waist and chest to keep participants in the orthostatic position. The tilt table protocol lasted 30 minutes. Initially, participants were placed in a vertical position up to 45° and remained in this position for 3 minutes. Next, they were tilted to 60°, where they remained for 2 minutes. Then verticalization was performed up to 75-85°, where they remained for another 25 minutes.

**Co-interventions:** Endotracheal aspiration was performed 30 minutes before the beginning of both verticalization position protocols. The critical care management of participants, including IMV parameters were left at the discretion of each center assistant team according to local protocols.

### **Randomization, washout, and bliding**

Subjects were randomized in an 1:1 ratio to one of two sequences of verticalization protocols: sitting position followed by passive orthostasis or passive orthostasis followed by sitting position. Participants were randomized on the same day they were deemed to be suited to participate in the study. Randomization was performed using blocks of different sizes and stratified by center. Allocation concealment was ensured through the use of a centralized webbased randomization plataform (REDCap, Vanderbilt University, Nashville, TN, USA). Researchers had access to intervention sequence only after the participants were registered on the platform. A washout window period (90 to 150 minutes) in which the patient was returned to bed in supine position (end of the first verticalization protocol) was applied between the two verticalization protocols to avoid the carryover effect. Considering the nature of the trial interventions, blinding was not feasible.

### **Statistical Analysis Plan**

Baseline categorical variables were described as absolute and relative frequencies, while baseline quantitative variables were expressed as mean and standard deviation (SD). Subjects were analyzed according to their randomization group, regardless of treatment they received. Paired Student's T test was used to compare the primary outcome between the two interventions. For secondary outcomes, categorical outcomes were assessed using the McNemar's test, symmetrical continuous outcomes were assessed using the Paired Student 's T test, and asymmetrical continuous outcomes were assessed using the Wilcoxon's signed-rank test. A significance level of 5% was set for all analyses.