

**Stability of Driving Pressure Changes During "Best Positive End Expiratory Pressure (PEEP)" Trial**

**NCT number: applied for**

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**Trial Protocol:**

During study periods, a pulmonary/critical care medicine fellow physician (fellow) will screen patients following intubations in Medical Intensive Care Unit (MICU) and Medical Critical Care Unit (MCCU). Following the intubation and initial stabilization (within 30 minutes of intubation), the fellow will increase PEEP by 3 followed by serial measurements of plateau pressure at 3 breaths, 30 seconds, 1 minute, 5 minutes, and 10 minutes. At the end of 10 minutes, PEEP will again be increased by 3, with repeat measurements of plateau pressure at 3 breaths, 30 seconds, 1 minute, 5 minutes, and 10 minutes. The PEEP would returned to the original value and the results will then be communicated to the treating ICU team.

Given that the post-intubation period is a critical time point in patient's ICU stays and risk of decompensation regardless of the performance of an "optimal PEEP trial". Fellow will remain at bedside throughout the trial and is to increase FiO<sub>2</sub> if patient oxygen saturation drops below 90%. If the patient develops hemodynamic or other instability, as determined by the fellow, the trial will be ended and the fellow will proceed with standard interventions to stabilize the patient. The results at time of instability will be recorded in addition to a qualitative description.

**Inclusion criteria:**

Adult patients >18 years of age

Undergoing intubation and mechanical ventilation in Medical Intensive Care Unit (MICU) or Medical Critical Care Unit (MCCU).

**Exclusion criteria:**

Prisoner

Pregnant

Age <18 years of age

Intensive Care Unit (ICU) team declines participation

Unstable oxygenation (requiring 100% FiO<sub>2</sub> to maintain saturations greater than 90% oxygen saturation following initial PEEP titration by primary team)

Hemodynamic instability: vasopressor requirement of >0.3 mcg/kg/min of norepinephrine or equivalent

Pneumomediastinum

Pneumothorax without chest tube

Previous enrolled in trial

Need for immediate travel out of ICU following intubation for procedures, tests

**Statistical plan:**

We based our power calculations around a small pilot study (Sahetya et al). They demonstrated a mean driving pressure at 15 minutes of 13.89 with standard deviation is 2.63 (based on personal communication with first author). Based on an effect size of 80% and alpha of 0.05, we

will use a sample size of 50 to obtain adequate statistical power to exclude a clinically significant difference of 1 mmHg. Citation: PEEP Titration to Minimize Driving Pressure in Subjects With ARDS: A Prospective Physiological Study. Sarina K Sahetya, David N Hager, R Scott Stephens, Dale M Needham, Roy G Brower. Respiratory Care May 2020, 65 (5) 583-589; DOI: 10.4187/respcare.07102