Prospective, Randomized, Multi-Center Trial of Lateral Trendelenburg Versus Semi-Recumbent Body Position in Mechanically Ventilated Patients For The Prevention of Ventilator-Associated Pneumonia

*Designed by the Gravity-VAP Network*
Prospective, Randomized, Multi-Center Trial of Lateral Trendelenburg versus Semi-Recumbent Body Position in Mechanically Ventilated Patients For The Prevention of Ventilator-Associated Pneumonia

(The Gravity-VAP Trial)

Designed by the Gravity-VAP Network

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Protocol Title: Prospective, Randomized, Multi-Center Trial of Lateral Trendelenburg versus Semirecumbent Position Body Position in Intubated Patients and Ventilator-Associated Pneumonia

Abbreviated Title: The Gravity-VAP Trial.

Identifying words: Ventilator-Associated Pneumonia, Semirecumbent Position, Trendelenburg

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### Duration of Study: Three years

### Number and Type of Subjects: Intubated and mechanically ventilated, sedated critical care patients

### Multi-Institutional Project: Yes
Précis

Title: Prospective, Randomized, Multi-Center Trial of Lateral Trendelenburg versus Semi-Recumbent Body Position in Mechanically Ventilated Patients For The Prevention of Ventilator-Associated Pneumonia

Abbreviated Title: Gravity-VAP trial

Objectives: This study is planned to compare, in patients sedated, intubated and mechanically ventilated, the efficacy and safety of the Lateral Trendelenburg position in comparison to the Semirecumbent Position to prevent incidence of ventilator-associated pneumonia.

Study Design: Multicenter, randomized, controlled clinical trial. The enrollment will last approximately 30 months. The analysis will last approximately 6 months. The entire duration of the study will be 36 months. The semirecumbent position and the lateral-Trendelenburg position will be recommended until patient is extubated.

Sample size/Interim Monitoring: This study will enroll a maximum of 800 patients. An interim analysis will be performed after 400 patients to determine stop of the study for futility, lack of safety, or proven efficacy

Inclusion Criteria:
1. Age ≥ 18 years
2. Patients expected to be oro-tracheally intubated for at least 48 hours or longer
3. Enrollment time window within 12 hours following intubation

Exclusion Criteria:
1. Current and past participation in an other intervention trial conflicting with the present study
2. Previous endotracheal intubation longer than 12 hours during the previous 30 days
3. Patients with documented bronchiectasis
4. Deep venous thrombosis or pulmonary embolism treated in the last 2 days
5. Cystic fibrosis
6. Witnessed pulmonary aspiration either prior or at intubation
7. Patients with increased intracranial pressure, brain edema; or medical conditions that can
worsen with increase in intracranial pressure

8. Patients with significant heart failure and activity impairment (Class III-IV of the New York Heart Association (NYHA))
9. Spinal cord injury
10. BMI > 35, or weight above 300 pound
11. Grade IV: Intra-abdominal pressure (IAP) > 25 mmHg or abdominal compartment syndrome (ACS), defined as a sustained IAP > 20 mmHg that is associated with new organ dysfunction / failure
12. Pregnancy
13. Orthopedic problems that will not allow the patient to be kept in one of the study positions

Efficacy:

Primary endpoint

The primary endpoint will be incidence of ventilator-associated pneumonia within the first 14 days of intubation, confirmed by quantitative microbiology analysis of either bronchoalveolar lavage (BAL) or mini-BAL fluids or secretions collected through protected specimen brush (PSB).

Secondary endpoints

1. Duration of mechanical ventilation
2. Duration of intensive care unit stay
3. Duration of hospital stay
4. Safety of the Semi-Recumbent and Lateral-Trendelenburg position
5. Use of Sedatives
6. Use of Antimicrobials
7. ICU mortality
8. Hospital mortality
9. 28 Days mortality
10. Assessment of nursing-related issues in the lateral-Trendelenburg position