

Title: The effect of lateral tilt on ventilation distribution in lungs assessed by electrical impedance tomography: A pilot prospective randomized study in neurocritical care

Short Title: N-LAT-EIT (Neurocritical care – LATeral – Electrical Impedance Tomography)

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PROTOCOL

The effect of lateral tilt on ventilation distribution in lung assessed by electrical impedance tomography: A pilot prospective randomized study in neurocritical care

N-LAT-EIT (Neurocritical care – LATeral – Electrical Impedance Tomography)

Study Objectives

Prevention of lung inhomogeneity is an essential part of preventive strategy in neurocritical care, reducing the risks of secondary brain damage from hypoxemia, hypo/hypercapnia or pneumonia. The investigators will examine the effect of lateral tilting (routinely used in critical care) on the lung inhomogeneity that will be analyzed by electrical impedance tomography (EIT). Two types of lateral tilting will be compared: manual positioning of body by nurse versus the bed tilting (15° lateral tilt, original company name (LINET) and product brand name Eleganza 5).

Type of study

1. Monocentric: Neurointensive Care Unit (NICU), Regional Hospital Liberec (research organization);
2. Prospective;
3. Randomized;
4. Intervention: parallel assignment;
5. Blind for statistics: statistics will only know type A or B randomization;
6. Patients: Pilot data in 50 patients, following a statistical evaluation, the study will continue with a total of 200 patients.

Entry criteria

1. Primary brain disease;
2. Hospitalization in NICU, Neurocenter;
3. Age >18 up to 99 years;
4. Unconsciousness;
5. Artificial pulmonary ventilation;
6. Available EIT device.

Exclusion criteria

1. Intracranial hypertension;
2. History of primary lung disease;
3. The terminal stage of the disease;
4. Refractory hemodynamic instability.

The primary aim

Atelectasis/collapse assessed by EIT or chest x-ray (CXR) at end of observation period.

The secondary aims

1. Evaluating oxygenation parameters;
2. Evaluating hemodynamic parameters: stroke volume variation (SVV) and cardiac index (CI) in one type of hemodynamic monitor;
3. Comparing staying in Neurocenter Neurointensive Care Unit and cost effectiveness between two groups;
4. Profiling pneumonia incidence between two groups.

Study groups (random assignment)

1. Manual positioning of body by nurse: left side, back, right side using positioning pillows;
2. Bed tilting: 15° lateral tilt, LINET Eleganza 5.

Study duration

Start of study: January 2020

End of study: pilot study after recruitment of 50 patients. Complete study after recruitment of 200 patients.

Statistical Analysis Plan

Running statistical analysis will be performed after recruitment of 50 patients. Ventilation distribution in lungs will be evaluated by EIT and in case of non-significant differences in detecting lung inhomogeneity and risk of pneumonia among group 1 and 2, the study will continue.

Complete study analysis will be performed after recruitment of 200 patients.

Continuous variables will be assessed using t-tests or Mann-Whitney tests depending on data distribution. Categorical variables will be assessed using chi-square tests. Multivariate logistic regression analysis will be used estimating the occurrence of pneumonia versus EIT related measures of lung inhomogeneity. For assessing the association between measured oxygenation, EIT derived parameters and ventilator parameters, the Pearson or Spearman correlation method will be used, depending on parameters' distribution.

Liberec, January 7th, 2020

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