

# **Prevention of pressure ulcer by lateral tilt bed in neurocritical care**

PULAT-NC (pressure ulcer – lateral – neurocritical care)

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# PROTOCOL

## **Prevention of pressure ulcer by lateral tilt bed in neurocritical care**

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### Study Objectives

Patient positioning is an essential part of a preventive strategy for neurocritical care patients. The aim of the study will be to determine whether the positioning of the bed (LINET Eleganza 5 - bed equipped with 15° lateral tilt; LINET Clinicare 20 - highly specified passive mattress, polyurethane foam with top viscoelastic layer) has different (worse, same or better) clinical outcome compared with manual patient's repositioning for prevention of pressure ulcer in the Neurointensive Care Unit (NICU).

### Type of study

1. Monocentric: NICU, Regional Hospital Liberec (research organization); where the standard preventive protocol of pressure ulcer in patients - without intracranial hypertension - positioning every 2 hours is being followed;
2. Prospective;
3. Randomized;
4. Intervention: parallel assignment;
5. Blind for statisticians: statisticians from a different institution will only know type A or B randomization;
6. Patients: 300 patients.

### Entry criteria

1. Primary brain disease;
2. Hospitalization in NICU, Neurocenter;
3. Age > 18 years;
4. Unconsciousness;
5. Artificial pulmonary ventilation.

### Exclusive criteria

1. Intracranial hypertension;
2. Decubitus on the skin upon admission;

### Primary outcome

1. Incidence of pressure ulcer.

### Secondary outcome

1. Stay in NICU;
2. Cost effectiveness.

### Study duration

Start of study: October 2019

End of study: pilot study after recruitment of 50 patients. Complete study after recruitment of 300 patients.

## Statistical Analysis Plan

Interim analysis will be performed after recruitment of 50 patients. Incidence of pressure ulcers in both groups will be evaluated and in case of non-significant difference between groups assessed by chi-square test, the study will continue.

Complete study analysis will be performed after recruitment of 300 patients.

Categorical variables will be assessed using chi-square tests. Continuous variables will be assessed using t-tests or Mann-Whitney tests as appropriate according to normality of data distribution. Age and gender will be controlled for in multivariate log-regression models build for prediction of pressure ulcer occurrence.

In Liberec, 27<sup>th</sup> August, 2019.  
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