TITLE (SHORT, 200 CHARACTERS MAX.):

VENTILATORY MANAGEMENT AND OUTCOME IN PATIENTS AFTER OHCA AND TARGETED TO HYPOTHERMIA OR NORMOTHERMIA: A SUBANALYSIS OF TTM 2

MAIN HYPOTHESES TESTED (2 MAX)

The aim of this sub-study is to describe and compare the changes in ventilator management and complications over time, as well as variables associated with 28-day hospital mortality in patients receiving mechanical ventilation (MV) after cardiac arrest. The hypothesis is that protective ventilation with lower tidal volume and lower driving pressure is associated with reduced risk to develop respiratory failure and pneumonia.

SINGLE CENTER [ ] , MULTICENTER [X]

All TTM 2 centers.

PICO

Patients: All patients admitted in ICU after OHCA included in TTM Trial. Patients dying within 24 hrs are excluded.

Intervention/Exposure/Prognostic factor: None

Comparison: Ventilatory management (Tidal volume – Plateau pressure – Driving Pressure – Gas-Exchange) and their effects on outcome in patients after OHCA.

Outcome: in-hospital mortality and length of stay in ICU and pulmonary complications.

DATA NEEDED FOR THE ANALYSIS (SPECIFY VARIABLES AND MOTIVATE ANY PROPOSED ADDITIONS TO THE ECRF)

Ventilatory management description in the first week: tidal volume – respiratory rate – plateau pressure – peep – Driving pressure - FiO2 – Gas exchange.

We proposed to add to eCRF the following data:

- tidal volume – respiratory rate – plateau pressure – peep – Driving pressure - FiO2 – Gas exchange (first week)
- Complications: complications arising during the course of the mechanical ventilation was defined as ARDS, pneumonia, sepsis and/or multi-organ failure (cardiovascular, respiratory, renal, hepatic and hematologic, defined as a score higher than two points on the SOFA scale. Pneumonia acquired during ICU stay was defined by modifying Centers for Disease Control and Prevention criteria which require the presence of a new radiographic infiltrate persistent for 48 hours or more plus a body temperature of more than 38.5°C or less than 35.0°C, a leukocyte count of more than 10,000/µ L or less than 3,000/µ L, purulent sputum or change in character of sputum, or isolation of pathogenic bacteria from an endotracheal aspirate. Additionally the CPIS score might be collected within the first week after ICU admission. Further CPIS score and its components is registered: 1) ICU admission; 2) at between 2nd and 3rd ICU day; 3) between 4th and 7th day.

LOGISTICS – HOW WILL ADDITIONAL DATA BE GATHERED?

Ventilatory data, are commonly registered during clinical practice. SOFA and CPIS require additional information, not always available in clinical routine practice.

BRIEF STATISTICAL ANALYSIS PLAN AND SAMPLE SIZE ESTIMATE

From a previous study (Sutherasan Y et al. Critical Care 2015), we expect a incidence of around 50 % of a composite outcome defined as ARDS, pneumonia, sepsis, multi-organ failure, or death within day 28. Enrolling at least 600 patients (i.e. half of patients to be recruited in TTM2), we expect to observe 300 occurrences of the composite outcome, therefore allowing us to include up to 30 covariates in a multivariable logistic regression to identify independent risk factors, including ventilation parameters.

FUNDING (IF APPLICBABLE)

None.

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