TITLE (SHORT, 200 CHARACTERS MAX.):

TRACHEOSTOMY AFTER CARDIAC ARREST AND QOL: A SUBANALYSIS OF TTM 2

MAIN HYPOTHESES TESTED (2 MAX)

The aim of this sub-study is to describe the prevalence of tracheostomy in patients after cardiac arrest and the 28-day hospital mortality in patients that did or did not receive tracheostomy.
A secondary aim is to investigate risk factors for tracheostomy and relationships between tracheostomy and quality of life.

SINGLE CENTER [ ] , MULTICENTER [X]

All TTM 2 centers.

PICO

Patients: All patients admitted in ICU after OHCA included in the TTM2 Trial. Patients dying within 24 h are excluded.

Exclusion:

Intervention/Exposure/Prognostic factor: tracheostomy and no tracheostomy (observational and according to physician decision)

Comparison: Tracheostomy and outcome in patients after OHCA.

Outcome: in-hospital mortality and length of stay in ICU – QoL

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

Date when the tracheostomy was performed (if performed).

Date of weaning from the mechanical ventilator.

Neurologic outcome as assessed in TTM2

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

Investigation of possible risk factors for tracheostomy. Patients who underwent tracheostomy and died within 30 d of admission (futile group) were compared with patients who underwent tracheostomy and survived more than 30 d after admission (non-futile group).

LOGISTICS – HOW WILL ADDITIONAL DATA BE GATHERED?

Data will be gathered by individual participants to the study. Each centre interested in this study, should nominate a responsible – coordinator.

BRIEF STATISTICAL ANALYSIS PLAN AND SAMPLE SIZE ESTIMATE

From a previous study (Sutherasan Y, Critical Care 2015), we expect that 14% of the patients will receive tracheostomy, and that the overall 28-days mortality will be around 50%. Therefore, including 600 patients (i.e. half of patients to be recruited in TTM2), should result in a population of about 520 non-tracheostomised and 80 tracheostomised patients. Therefore, with a sample size of 600 patients we would achieve an 80% power (1-β) to detect a $\pm$ 17% difference in mortality between patients that did or did not receive tracheostomy at an α level of 0.05.

FUNDING (IF APPLICBABLE)

None.

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