

PRINCESS2 SUBSTUDY

Determinants of Infection after OHCA

Study objective

This substudy aims to identify and evaluate risk factors, protective factors, and preventive measures for respiratory tract and other nosocomial infections in patients after out-of-hospital cardiac arrest (OHCA), and to assess the timing of these factors and their influence on morbidity and mortality. A secondary objective is to explore whether upper airway cooling affects oropharyngeal flora and, consequently, the incidence of respiratory tract infections.

Hypothesis

1. Risk factors and protective factors, as well as preventive measures for respiratory tract and other nosocomial infections after OHCA and their respective timing differ between centers and individual patients and influence morbidity and mortality.
2. Upper airway cooling may have an effect on oropharyngeal flora and thus on the incidence of respiratory tract infection, which is caused mainly by oropharyngeal flora.

Study Design/Methods

All subjects enrolled in the PRINCESS2 trial at participating sites may be included in this substudy. Data will be collected of potential risk and protective factors, preventive measures and the characteristics of episodes of nosocomial infection (respiratory tract, bacteremia, urinary tract and “other”) occurring during the first 30 days after inclusion. Baseline endotracheal aspiration sample will be taken for bacterial culture. Data will be recorded in a substudy eCRF, attached to the PRINCESS2 trial core eCRF. Comparisons will be made of risk/protective factors and interventions in subjects with and without infection, and of nosocomial infection incidence and types in subjects who underwent trans-nasal cooling vs. the control group. Key outcomes are incidence and type of nosocomial infection, associated morbidity (length of respiratory support and ICU stay, mRS) and mortality at 30 days. Hazard ratios will be presented for infection and type of infection (ventilator-associated pneumonia, bacteremia, urinary tract infection), multivariate analyses will be made for risk and protective factors, and survival analysis.

Contact

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