

Prevention of early ventilation-acquired pneumonia (VAP) in comatose brain-injured patients by a single dose of ceftriaxone: PROPHY-VAP study protocol, a multicentre, randomised, double-blind, placebo-controlled trial

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INTRODUCTION: Ventilator-associated pneumonia (VAP) is the first cause of healthcare-associated infections in intensive care units (ICUs) and brain injury is one of the main risk factors for early-onset VAP. Antibiotic prophylaxis has been reported to decrease their occurrence in brain-injured patients, but a lack of controlled randomised trials and the risk of induction of bacterial resistance explain the low level of recommendations. The goal of this study is to determine whether a single dose of ceftriaxone within the 12 hours postintubation after severe brain injury can decrease the risk of early-onset VAP.

METHODS AND ANALYSIS: The PROPHY-VAP is a French multicentre, randomised, double-blind, placebo-controlled, clinical trial. Adult brain-injured patients (n=320) with a Glasgow Coma Scale ≤ 12 , requiring mechanical ventilation for more than 48 hours, are randomised to receive either a single dose of ceftriaxone 2 g or a placebo within the 12 hours after tracheal intubation. The primary endpoint is the proportion of patients developing VAP from the 2nd to the 7th day after mechanical ventilation. Secondary endpoints include the proportion of patients developing late VAP (>7 days after tracheal intubation), the number of ventilator-free days, VAP-free days and antibiotic-free days, length of stay in the ICU, proportion of patients with ventilator-associated events and mortality during their ICU stay.

ETHICS AND DISSEMINATION: The initial research project was approved by the Institutional Review Board of OUEST III (France) on 20 October 2014 (registration No 2014-001668-36) and carried out according to the principles of the Declaration of Helsinki and the Clinical Trials Directive 2001/20/EC of the European Parliament relating to the Good Clinical Practice guidelines. The results of this study will be presented in national and international meetings and published in an international peer-reviewed journal.

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