

PRINCESS2 SUBSTUDY

Ventilation Consistency to Enhance Resuscitation Outcomes Sub-study (VICEROY)

Study objective

This substudy aims to investigate whether real-time ventilation feedback via an active EOLife device improves the restoration of spontaneous circulation (ROSC) and other clinical outcomes compared to a sham EOLife device, in patients suffering out-of-hospital cardiac arrest with shockable rhythm.

Hypothesis

1. Primary H0: Restoration of spontaneous circulation at emergency department (ED) arrival is identically distributed between the control group (sham EOLife device) and the intervention group (active EOLife device).
2. Secondary H0: Survival to discharge, neurologic status at discharge, hospital-free survival, and serious adverse events, are identically distributed between the control group (sham EOLife device) and the intervention group (active EOLife device).

Study Design/Methods

OHCA patients with a shockable first rhythm enrolled in the PRINCESS2 trial will be randomized by participating EMS providers to either a) intervention; active EOLife device providing real-time ventilation feedback until ED arrival or b) control; sham EOLife device without ventilation feedback. The EOLife device (Archeon Medical Systems, Lille, France) is intended to be connected in-line with a bag-mask or advanced airway circuit and gives real-time ventilation feedback and record how ventilation is performed, while the sham device records without feedback. The device will be applied as soon as feasible after the first rhythm analysis. VICEROY study data will be retained in the ED upon arrival and recorded in the substudy eCRF, attached to the PRINCESS2 trial core eCRF. Primary outcome is ROSC at ED arrival. Secondary outcomes are survival to discharge, neurologic status at discharge, hospital free survival, serious adverse events, quality of ventilation. 524 (262 per group) patients are required to detect an increase in a primary outcome of ROSC from 36% in the control group to 48 % in the intervention group (80% power, two-sided alpha =0.05).

Contact

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