PRINCESS2 SUBSTUDY

Intra-Arrest Cooling Compared to Normothermia in ECPR Patients

Study objective

This substudy aims to evaluate whether intra-arrest hypothermia followed by systemic hypothermia in extracorporeal cardiopulmonary resuscitation (ECPR) patients improves neurologically intact survival compared to standard ECPR care without hypothermia. The study also aims to assess safety and feasibility of intra-arrest cooling in ECPR patients.

Hypothesis

Intra-arrest cooling and subsequent cooling at ICU in ECPR patients improves neurological survival compared to standard ECPR-care with no hypothermia.

Study Design/Methods

This study will include patients with refractory OHCA with initial shockable rhythm, enrolled in the PRINCESS2 trial and eligible for ECPR. Patients will be treated according to allocation group in the main trial (intra-arrest hypothermia followed by systemic hypothermia to 33°C for 24 hours (intervention) or standard of care with fever control for 72 hours (normothermia). Data on time to events (prehospital, cannulation, ECMO-start), factors at hospital arrival, angiographic findings and PCI, additional circulatory support and complications will be recorded in a substudy eCRF, attached to the PRINCESS2 trial core eCRF. Primary outcome is survival with complete neurologic recovery at 90 days, defined as mRS 0-1. Secondary outcomes are overall survival at 90 days, composite safety endpoint (major bleeding, refractory circulatory shock, refractory ventricular arrhythmias, need for additional organ support), feasibility (event times related to cooling, time to target temperature). The aim is to include 100 patients.

Contact

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ULTRAFAST HYPOTHERMIA IN CARDIAC ARREST