PRINCESS2 SUBSTUDY

PRINCESS2-MI

Study objective

This substudy aims to investigate the impact of ultrafast hypothermia on local temperatures in the infarct related artery in out-of-hospital cardiac arrest(OHCA) patients with ST-elevation myocardial infarction (STEMI), and the potential reduction of reperfusion injury, thereby limiting infarct size and enhancing cardiac recovery.

Hypothesis

1. Ultrafast hypothermia in cardiac arrest can sufficiently induce hypothermia locally in the infarct related artery in patients with cardiac arrest due to anterior ST elevation MI.
2. Reperfusion injury in the infarct related territory can be reduced to limit infarct size and enhance cardiac recovery such as need of mechanical/inotropic support at the intensive care.

Study Design/Methods

OHCA patients enrolled in the PRINCESS2 trial with a STEMI due to proximal LAD or LM occlusion, (TIMI 0-1 flow), will be included in the substudy. Temperature measurements will be taken from the LAD just proximal of the occlusion and after reperfusion in both patients randomized to prehospital hypothermia (intervention) and standard care (control). A coronary guidewire used for intracoronary diagnostics will be inserted in the LAD (Coroventis™/Abbott™) and automatic temperature measurement will be recorded and stored in the system. The same guidewire can be used for PCI. Additional data, such as hemodynamic parameters will be specified. Echocardiographic assessments will be made at discharge and 60-90 days, with additional MRI to evaluate infarct size. Data will be recorded in a substudy eCRF, attached to the PRINCESS2 trial core eCRF. The sample size is set to 80 patients.

Key outcomes will include:

1. Cardiac/hemodynamic performance in the first 72 hours (LVEF/VTI + other parameters, Troponin, Lactate clearance, NTproBNP, need for vasopressors/inotropic agents/arrhythmias).

2.*Feasability and safety aspects of ultrafast hypothermia prior to reperfusion* (time to revascularization, arrythmias, bleeding events during catheterization).

3. *Infarct size and reperfusion injury* (assessment through echocardiography at discharge and at 60-90 days, with additional MRI evaluation if feasible).

Contact

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ULTRAFAST HYPOTHERMIA IN CARDIAC ARREST