

## PRINCESS2 SUBSTUDY

### **Impact of Therapeutic Hypothermia on Stent Thrombosis in Comatose Survivors of OHCA undergoing Acute PCI**

#### **Study objective**

This substudy aims to evaluate whether therapeutic hypothermia (32-34°C) increases the risk of stent thrombosis in comatose survivors of out-of-hospital cardiac arrest (OHCA) who undergo acute percutaneous coronary intervention (PCI).

#### **Hypothesis**

Therapeutic hypothermia (32-34° C) does not increase the risk of stent thrombosis in comatose survivors of OHCA after acute PCI.

#### **Study Design/Methods**

OHCA patients enrolled in the PRINCESS2 trial undergoing acute PCI at hospital admission (predominately with STEMI in post resuscitation ECG) will be included in this substudy. Index CAG and PCI (anatomy/pathology and PCI description), periprocedural and postprocedural antiaggregation /anticoagulation will be recorded. CAG/PCI if ST will be repeated if stent thrombosis is suspected. Data will be recorded in the substudy eCRF, attached to the PRINCESS2 trial core eCRF. The hypothermia group and control group will be compared for the primary outcome; stent thrombosis during ICU stay confirmed by repeat coronary angiography triggered by clinical criteria (new ST elevation, hemodynamic instability, recurrent cardiac arrest, unexpected troponin rise). Given that approximately 40% of OHCA present with STEMI in post resuscitation ECG and undergo immediate CAG/PCI, about 500 patients may be enrolled (ie 250 per group). The anticipated stent thrombosis rate is estimated to be between 5-15%, with no significant difference expected between hypothermia and normothermia groups.

#### **Contact**

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