

EARLY-NEURO substudy description for STEPCARE

Background:

Prediction of functional outcome is not recommended prior to 72 hours after cardiac arrest according to ERC/ESICM guidelines. Most prognostic examinations, however, can be performed within the first 1-2 days post-arrest, and prediction of outcome is often based on results from these early examinations. One group of patients may display all prognostic signs of severe brain injury within the first day post-arrest. Nonetheless, withdrawal of treatment is discouraged until at least 72 hours have passed. The EARLY-NEURO substudy aims to examine whether earlier neuroprognostication could be performed safely at 24 hours after randomization in patients with severe brain injury and whether the level of sedation may influence accuracy of examinations. Early neuroprognostication could reduce suffering and unnecessary treatment in selected patients with no perspective of regaining consciousness. Early neuroprognostication with brain injury markers could also help identify patients without brain injury, where continued treatment is lifesaving.

Our main hypotheses are:

- 1) The combination of clinical examinations, the novel brain injury marker Neurofilament light (NFL), electroencephalography (EEG), and head computed tomography (CT) predict poor functional outcome at 24h post-randomization without false positive predictions.
- 2) Any ERC/ESICM recommended method fulfilling criteria for a poor outcome will have highly elevated blood levels of NFL, indicating the presence of severe brain injury.
- 3) Extensive sedation will not affect the prognostic accuracy of our examinations.

Methods:

Patients who are unconscious at 24 hours after randomization are examined with CT, EEG and blood biobank samples are collected at 12, 24, 48 and 72 hours post-randomization. Intensive care treatment, neurological prognostication, and criteria for withdrawal of life-sustaining therapy are according to the STEPCARE protocol and ERC/ESICM criteria.

Eligibility criteria for EARLY-NEURO sites are:

- 24/7 availability for collection and processing of biomarker samples
- 7-day availability for CT and EEG examinations.
- Sites commit to exporting all original neuroprognostic examinations (imaging and neurophysiology) for retrospective evaluation by investigators blinded to clinical data.

Site investigators interested in joining the EARLY-NEURO substudy please feel free to contact Marion Moseby-Knappe (marion.moseby_knappe@med.lu.se).