Official title:

Augmented Multimodal Neurologic Monitoring in High Risk Survivors of Cardiac Arrest

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Trial Protocol

PRIOR TO APPROACHING SURROGATE(S): The Post-Cardiac Arrest Service (PCAS) physician will have been consulted to evaluate and treat patients eligible to be subjects in this research study. They will have already made the decision to offer invasive multimodal neurological monitoring to the patient, and surrogate consent for this non-research clinical procedure will have been obtained. A study investigator will be contacted directly by the PCAS physician.

Patient surrogate(s) currently provide procedural consent for invasive monitoring prior to ICU admission, since multimodal neurologic monitoring requires triage to a neuroscience ICU. We plan to approach potential research subjects after procedural consent is obtained but before the procedure is performed. This timing is necessary because, to ensure sterility, the monitoring probes are placed at the same time as the intracranial access bolt is placed (i.e. these steps are components of the same larger procedure). The eligibility requirements for invasive neurologic monitoring for CLINICAL purposes and participation as a subject in this RESEARCH proposal are identical, and no specific screening for research purposes will be necessary.

CONSENT TIMING: The patient's surrogate(s) will be approached by research study staff for discussion of the present research protocol only AFTER they have discussed all aspects of clinical care with the PCAS physician, had the opportunity to meet with a social worker, and only if they have voiced willingness to the PCAS physician to discuss participation in the present research protocol. This will occur PRIOR to placement of the intracranial access bolt (clinical care), since the monitoring probes are placed at the same time as the intracranial access bolt is placed (i.e. these steps are components of the same larger procedure).

RESEARCH PROCEDURES: Patients who are candidates for multimodal neurological monitoring, whose surrogates have provided procedural consent as part of routine clinical care, and additionally agree to participation in the present proposal would undergo placement of the same intracranial access bolt, which would be fitted with routine clinical monitors, with the addition of the intracortical EEG probe (research). Intracranial access bolts will be placed by the neurosurgery team in the ICU under sterile conditions as per their usual protocol. NOTE: At study initiation, cerebral blood flow monitoring was deemed to be a research intervention and thus addressed in the initial protocol; on subsequent IRB review we were asked to change this to part of the routine bundle of CLINICAL monitoring. No subjects were enrolled subsequent to this change.

For this study, a transcortical multi-contact EEG electrode (Spencer Depth Electrode, AD-Tech, Racine, WI; FDA Regulation Number 882.1330) would be introduced via an otherwise-unused lumen. When fully inserted, the probe extend several millimeters below the surface of the brain parenychma. This monitoring system is used locally in other neurologically critically ill patient populations, such as for routine for neurophysiologic monitoring during epilepsy surgery. Our neurophysiology/EEG attending group and technologists are familiar with its use. The nondisposible components of the monitoring

system are already owned by the institution and available for use in this project.

Procedures will be performed in the usual sterile fashion at the bedside of patients in a neuroscience intensive care unit (4G, 4F or 5F) by Neurosurgery on call. Insertion of this device requires ~5-10 minutes to perform. Patients will require no additional analgesia or sedation beyond what is already provided as standard of care during post-cardiac arrest resuscitation.

USE AND INTERPRETATION OF DATA FROM RESEARCH DEVICE: The information obtained from the research monitor will be displayed at the subject's bedside and available for interpretation and use by the clinical providers (physicians, nurses, housestaff) at all times. Intracortical EEG data will be monitored in parallel with surface EEG recordings by the neurophysiology attending responsible for interpreting continuous EEGs (rotating call schedule). Generally, the attending reading continuous EEG is in communication with the Post-Cardiac Arrest Service and ICU physicians at least daily to communicate their interpretations, but communication occurs more frequently if there are seizures or other malignant EEG patterns that require intervention.

No access to monitoring data will be withheld or delayed, and neither investigators nor clinicians blinded. At times, the investigators will also act as the subject's clinical provider. Clinical decisions driven by the experimental monitors will be made solely by the ICU team in charge of the patient's care. These may include the use of antiepileptic or sedating medications to treat seizures. Since seizures are significant determinants of the evolution of secondary brain injury in hypoxic-ischemic encephalopathy, we feel that it would be unethical to subject these patients to the risks of monitoring without the potential to benefit from the intervention. The study investigators will be available to discuss the interpretation of the experimental monitoring data, but clinical management in response to these data will not be dictated by research protocols.

DURATION OF STUDY PROCEDURES: The device will be left in place until such time as the intracranial access bolt is deemed unnecessary by the Critical Care Medicine service treating the patient, usually about 5 days after placement. At the time of removal, the bolt and all of its contents will be removed by the neurosurgical service.

STATISTICAL ANALYSIS PLAN: Descriptive statistics will be use to summarize population characteristics and the frequency of outcomes of interest in this study.