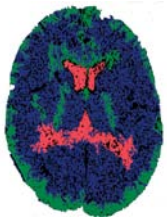

Neurological Emergencies Treatment Trials

Department of Emergency Medicine
Neuro Emergencies Research
University of Michigan

24 Frank Lloyd Wright Dr.
Lobby H, Suite 3100
Ann Arbor, MI 48106

734-232-2142
Fax734-232-2122

To: NETT Investigator and Coordinators
From: Robert Silbergleit, MD
Date: 25 January 2011
Re: Record review preparatory to research in acute spinal cord injury

As we have previously discussed, NETT is developing a clinical trial of induced hypothermia in patients with acute spinal cord injury called ARCTIC. We have also previously discussed the need for more detailed information about the timing of arrival and clinical characteristics of potential subjects in this trial.

Attached is an instruction sheet to assist in preparing your local regulatory documentation to allow you to review medical records to help optimally design a multicenter clinical trial of hypothermia as neuroprotection in patients with acute spinal cord injury. Please cut and paste as needed from this document in preparing your local materials. Also attached is the record review form. This can be included with your regulatory information.

This record review preparatory to research is not research and should be exempt from IRB review, and is permitted under section 164.512(i)(1)(ii) of the Privacy Rule (HIPAA). Please consult your own institutions rules for the review process for this category of proposal. At some institutions the IRB itself needs to review and provide an exemption from review, and/or an institutional privacy board may need to review the HIPAA compliance.

Use the data collection form to report all screened and all potentially eligible patients. The eligibility portion of this form should be completed for all screened patients, but the full form should only be completed on potentially eligible patients (those without any of the exclusion criteria in the box below). Screen all patients with acute traumatic cervical spinal cord injury (ICD-9 codes 806.0-806.1, 952.0 or equivalent from alternate coding system). Each hub is responsible for screening enough patients to identify their eight most recent consecutive potentially eligible patients. This data form should be completed in entirety (both sides) for those 8 patients. Submit the 8 fully completed forms as well as all the partially completed screening forms. For purposes of this chart abstraction Hubs may at their discretion draw from a single hospital that they expect to be their primary site, or from all the hospitals at their site that they expect to participate in ARCTIC.

Ideally, we would like to have these reviews collected within the next 3 months. Thank you for your hard work in these efforts.

NETT record review preparatory to research in acute spinal cord injury

Project Summary:

Our institution is a participating site in the Neurological Emergencies Treatment Trials (NETT) network, an NIH funded clinical trials network focusing on acute neurological injuries and illnesses. The NETT is in the process of developing a clinical trial of a neuroprotective therapy for patients with acute spinal cord injury (SCI). Neuroprotective strategies require rapid initiation of treatment in the emergency department as early as possible after injury. To optimally design a clinical trial we need very granular information about how quickly patients with SCI present to the emergency department and how quickly their injuries are currently assessed and treated. Adequate information to design the trial is not available in published or otherwise available aggregate data. In this project, each proposed enrollment site will retrospectively identify and review the records of previously treated patients with SCI at their site, and complete a two-sided single page data collection instrument for each patient. The chart review instrument is attached to this proposal. Only de-identified forms from all sites will be sent to the NETT CCC. The collected information will only be used to help select trial design parameters for the proposed clinical trial. They will not be used to determine any generalized medical knowledge, and will not be used in any research publication.

Estimated Duration of Study:

6 months

Number of records to be reviewed:

Sufficient records will be screened by ICD9 or equivalent coding, to identify 8 charts of patients meeting predefined criteria described on the record review form. Complete record review forms from those 8 charts, and partial forms from all other screened charts will be collected.

Application Type:

Activities not regulated as human subjects research

Reason proposal is Not Regulated

Pre-review of clinical data sets - activities (e.g., review of medical data, etc.) intended only to assess the feasibility of future research.

Investigator affirms:

(i) The use or disclosure is sought only to review PHI as necessary to assess the feasibility of future research; and (ii) no identifiers linking individuals to their PHI will be retained by the researcher after the feasibility review is complete.

Sponsor:

The proposed study does not involve any independent external or internal sponsorship or support

NETT Spinal Cord Injury Chart Abstraction in preparation of ARCTIC
Review preparatory to research conducted under section 164.512(i)(1)(ii) of the Privacy Rule (HIPAA)

Entry criteria instructions:
Use this data collection form to report all screened and all potentially eligible patients. The eligibility portion of this form should be completed for all screened patients, but the full form should only be completed on potentially eligible patients (those without any of the exclusion criteria in the box below). Screen all patients with acute traumatic cervical spinal cord injury (ICD-9 codes 806.0-806.1, 952.0 or equivalent from alternate coding system). Each hub is responsible for screening enough patients to identify their eight most recent consecutive potentially eligible patients. This data form should be completed in entirety (both sides) for those 8 patients. Submit the 8 fully completed forms as well as all the partially completed screening forms. For purposes of this chart abstraction Hubs may at their discretion draw from a single hospital that they expect to be their primary site, or from all the hospitals at their site that they expect to participate in ARCTIC.

Provide a sequential code to ensure that only unique patients are being reported. To ensure the record is de-identified, this code should not be linkable to the patient at the time the form is submitted.	
Subject Code:	
Hub:	
Hospital:	

If over 90 or older state ">89" rather than actual age to meet HIPAA de-identification rules	
Age:	

Answer in free text or select from one of the categories below				
Mechanism of injury:	○ MVC	○ Diving	○ Assault	○ Fall
	○ Other (specify):			

Exclusion criteria: Please mark any exclusion item clearly present. It is understood that the accuracy of screening for exclusion criteria by chart review is quite limited. Equivocal determinations should not be marked.
○ Rapidly improving exam in ED
○ Severe non-CNS injury (e.g., ISS > 25)
○ Significant traumatic brain injury (GCS < 13 or abnormal head CT)
○ Penetrating SCI
○ Unable to give informed consent
○ Prisoner or ward of the state
○ Pregnancy
○ Previous SCI
○ History of cardiac arrhythmia
○ Unknown cause for impairment
○ Languages without local expertise

Hospital Course, Duration, and Discharge Disposition (only complete this section and back of form for eligible patients)	
Length of initial ICU stay (days)	
Length of acute care hospital stay (days)	
Complications during acute hospital stay	○ Pneumonia ○ Urinary tract infection ○ Deep venous thrombosis or pulmonary embolism ○ Systemic bleeding requiring transfusion
Survival to Discharge?	○ Dead at discharge ○ Alive at discharge

First documented core body temperature			
Temp: ○ Fahrenheit ○ Celsius	Time (hh:mm):	Route: ○ oral ○ rectal	○ bladder ○ axillary ○ tympanic

Key Events and Time Points		Hospital day (calendar day of admission is 0)	Time (hh:mm) on 24 hour clock
Injury occurred at:		0	
Primary ED arrival:		0	
Secondary ED arrival (if transfer)			
Admission to ICU:			
Air medical or other critical care transport service (if yes, then time team first contacted patient):	○ yes ○ no		
Endotracheal intubation? (if yes, time performed)	○ yes ○ no		
Did patient receive high dose methyprednisolone? (if yes, time of initial administration)	○ yes ○ no		
MRI of cervical spine? (if yes, timestamp on first study)	○ yes ○ no		
Closed reduction and decompression? (if yes, time procedure initiated)	○ yes ○ no		
Surgical decompression of SCI? (if yes, time of OR arrival)	○ yes ○ no		
Other surgery? Specify: (if yes, time of OR arrival)	○ yes ○ no		

Assessment of injury by day/time: use this table to record one or more of these four assessments. If possible please complete at least one row for each stage of care. Record what was reported. E.g. if only a motor level was reported then only record that here and leave the other boxes blank. Emphasize the early time points, and the first report of each type of assessment. If different levels are reported for right and left sides, use the more caudal (less severe, lower level, higher number).

Stage of care	Hospital Day	Time (hh:mm)	Motor level	Sensory level	ASIA grade	ASIA score
○ Prehosp ○ ER ○ OR ○ ICU ○ Floor ○ Other					○ A ○ B ○ C/D	
○ Prehosp ○ ER ○ OR ○ ICU ○ Floor ○ Other					○ A ○ B ○ C/D	
○ Prehosp ○ ER ○ OR ○ ICU ○ Floor ○ Other					○ A ○ B ○ C/D	
○ Prehosp ○ ER ○ OR ○ ICU ○ Floor ○ Other					○ A ○ B ○ C/D	
○ Prehosp ○ ER ○ OR ○ ICU ○ Floor ○ Other					○ A ○ B ○ C/D	
○ Prehosp ○ ER ○ OR ○ ICU ○ Floor ○ Other					○ A ○ B ○ C/D	
○ Prehosp ○ ER ○ OR ○ ICU ○ Floor ○ Other					○ A ○ B ○ C/D	