November 9, 2018

HOBIT NEWS

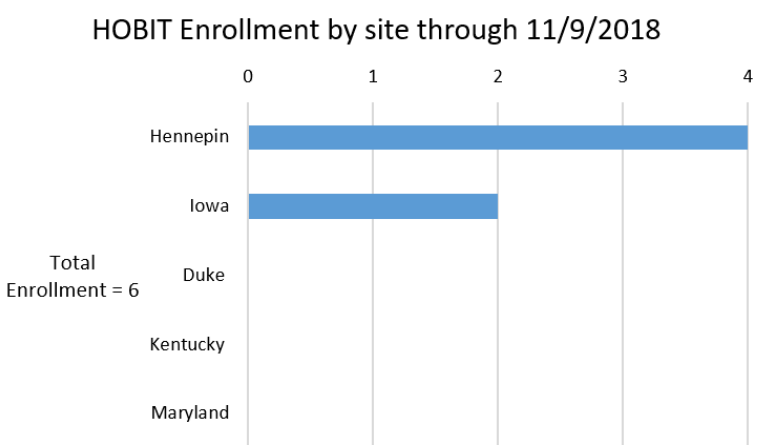
Hyperbaric Oxygen Brain Injury Treatment Trial Newsletter

Reminder:

+The next NETT/ SIREN Steering Committee Meeting is Nov 28th at 12pm EST

Hennepin—Participant Enrolled

Congrats to Hennepin County Medical Center on enrolling their 4th participant!



HOBIT Updates

Regulatory Document Approval Parameters

We are now requiring that the PI's CV include previous clinical trial/human subject's research experience. We'll be reaching out to sites that do not currently include this information in their PI's CV. Please refer to the Regulatory Document Approval Parameters for details.

MOP Updates

Updates have been made to the following sections in the MOP:

Subject Eligibility (section 3.2) - Statement added—

As per the protocol, patients unable to perform activities of daily living (ADL) without assistance prior to injury will be excluded. This to avoid enrolling subjects in whom the confounding effects of pre-injury disability will limit accurate assessment of functional disability post-TBI. For further clarification, our definition of "unable to perform ADL" includes patients with pre-existing neurologic disease (e.g. TBI, stroke, or neurodegenerative disorder) with confounding residual neurologic deficits. Please call the HOBIT PI line for any questions regarding the eligibility of a potential subject.

Study Intervention (section 3.4) Statement added—

The only study specific procedures performed in HOBIT are HBO treatments and myringotomy. All other procedures performed in caring for these severely injured subjects should be performed only if clinically indicated.

Conducting the GOSE Assessments (section 3.6.1) Please review section carefully. New information about timing of assessments, training of assessors, quality assurance procedures for GOSE assessors, and using the Ipad to record assessors QA sessions.

Conducting the GOSE Assessments (section 3.6.1) Statement added—

Monthly Follow-up Interview

The site study coordinator will hold monthly follow-up phone calls with all enrolled subjects/LAR during their time of enrollment (first 6 months post-randomization) and maintain a log of these calls. These calls are essential to maintaining contact with subjects/LAR and decreasing the likelihood of "loss to follow-up" at the 6-month visit. During these calls, study coordinators should inquire about the occurrence of any adverse events and ensure that subject/LAR's contact information is accurate and not expected to change in the coming month. The Monthly Follow-up Log CRF should be completed after these calls. monthly interviews with subjects, whether in-patient or post-discharge. There will be a total of six (6) follow-up interview calls. If the subject or relative/caregiver/friend is unable to be contacted, there should be a note added to reflect the attempt(s). If the subject has experienced any adverse events since last contact, the coordinator must complete Form 104 Adverse Event. The AE should be reported in WebDCU under the most recent visit (Hospital Discharge, Day 30, etc.).

Subject Monitoring During HBO Dives (section 3.7.4) statement added-

(for example for the subject randomized to HBO at 2.0 ATA without NBH, depth is when they reach 2.0 ATA).

For subjects assigned to NBH only, record the highest brain tissue PO2 achieved during NBH treatment.

Preventing Ventilator-Acquired Pneumonia (section 3.10.3) New section added—

The process of deflating the endotracheal tube (ETT) cuff and replacing the air with liquid can place subjects at risk for ventilator-acquired pneumonia (VAP) because pooled and contaminated secretions in the oropharynx (above the ETT) may enter the lungs placing subjects at risk for VAP if the right precautions are not taken. The hyperbaric cuff exchange procedure (HYCEP) will help minimize this risk. To attain competency in performing the HYCEP procedure, we have developed an educational activity for respiratory therapist and other study personnel who will be involved in replacing the air in the ETT cuff with liquid. This activity consists of:

1. A video demonstrating how to remove air from the endotracheal tube cuff and replace it with sterile solution (e.g. saline) prior to initiating hyperbaric oxygen treatments. watch video here (available in the HOBIT toolbox)

2. A skills and competency validation that we strongly recommend be completed by all who will be involved with exchanging the ETT cuff from air to normal saline; complete competency validation here (available in the HOBIT toolbox)

We realize that each institution may have their own policy and procedure for deflating and re-inflating an EFF cuff. However, for staff involved with HOBIT Trial subjects and involved with

Key bullet points when conducting the HYCEP

DO	DON'T
1. Use 2 caregivers when conducting this procedure. 2. Suction lung fields with the inline catheter. 3. Suction oropharynx with a yankauer. 4. Suction superior to the ETT cuff with a properly sized catheter eg: 14 french suction catheter (suction from the different sides of the ETT). 5. Use an appropriately sized ETT and cuff that will prevent oropharyngeal secretions from draining into the airway. 6. Prior to suctioning out the air from the cuff, give three breaths using the Bag Valve Mask and hold the third breath. The positive pressure from holding the third breath will prevent secretions from falling down into the airway when the cuff is deflated. 7. Chart and label that the cuff has been changed to NS for the HOBIT Trial. 8. Use the minimal leak technique to verify proper cuff pressure. 9. Ensure ETT is firmly secured from movement as much as possible. This is especially important during transport.	1. Do not change the ETT cuff back and forth between air to normal saline between HBO treatments. 2. Do not force or overfill the cuff with normal saline. 3. Do not assume that the subglottic suction port will remove all of the subglottic secretion above the cuff. 4. Do not use air to adjust the cuff pressure after it has been filled with NS or sterile water.