Hyperbaric Oxygen in Brain Injury Treatment Trial

HOBIT NEWSLETTER

HO$_2$BIT

May 27, 2022

Congrats to our Recent Enroller!

Hennepin County Medical Center

UPCOMING MEETINGS

SIREN Study Coordinator Call
Tuesday, June 7, 2022 1:00pm ET

GOSE Quarterly Meeting (Small Group)
Wednesday, June 8, 2022 12:00pm ET

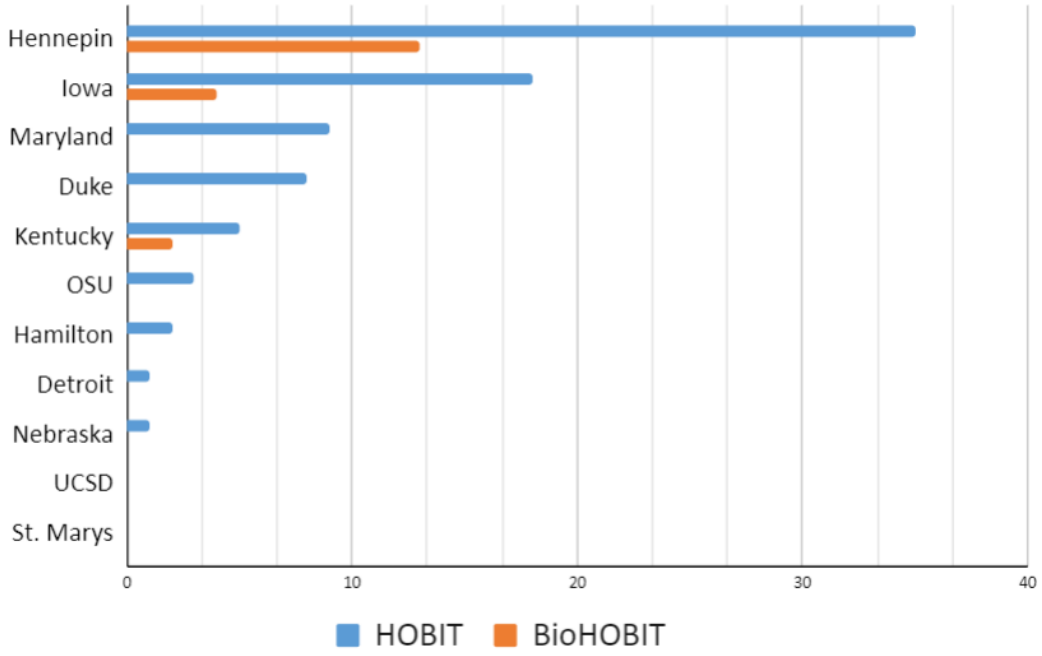
CQIP
Monday, June 13, 2022 1:00pm ET

SIREN Steering Committee
Wednesday, June 22, 2021 12:00pm ET

ENROLLMENT

HOBIT: 82 BioHOBIT: 19

** Aim to enroll every HOBIT subject in BioHOBIT **



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UPDATES & RESOURCES

Recent MOP Changes

Recent changes are highlighted in yellow

3.4 Study Intervention
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Timing of HBO dives and NBH treatments

The first HBO / NBH only treatment / dive is administered after randomization and within 8 hours of arrival at the enrolling hospital. For participants requiring a craniotomy/craniectomy or major surgical procedure, the first HBO / NBH only treatment can be initiated within 14 hours of arrival at enrolling hospital. The second HBO dive / NBH only treatment will be administered at least 8 hours following the first dive/treatment but no more than 14 hours after the first dive/treatment. Subsequent dives/NBH treatments will be administered at 12 hour intervals (+/- 2 hours) for a maximum of 10 dives/treatments or until the subject is following commands or determined to be brain dead. If the second dive/treatment cannot be administered within 14 hours of the first dive/treatment, then the next dive/treatment will be the third dive/treatment. If this occurs, call the PI hotline to discuss the timing of the third dive/treatment.

For subjects randomized to the HBO + NBH or NBH only groups, a clinician should place an order for the NBH treatment. This will allow tracking of the start and stop times of NBH treatment. Each NBH only treatment should not be administered for more than 4.5 hours (+/- 30 minutes)

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. Myringotomy is not required in subjects assigned to the NBH only or the control (no hyperoxia) group.

3.10.2 Preparation of the Severe TBI Subject for HBO2
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As discussed above, the lung is particularly susceptible to damage by hyperoxia because of the large surface area exposed to O2 in the lungs. Subjects with severe TBI are prone to the development of atelectasis and ventilator-acquired pneumonia. It is frequently difficult to distinguish the relative impact of an initial lung contusion and/or aspiration from the possible toxicity of HBO2 therapy. Based on our past experience, subjects should not undergo HBO2 therapy if the P/F ratio is $\leq$ 200. If the subject improves to the point that the P/F ratio is > 200 at any time during the first 5 days after randomization, treatments may be resumed. Subsequently, treatments may be continued if the P/F ratio remains above 200. Similarly, if PEEP requirements are > 10 cm of water, HBO2 /NBH only treatments are temporarily discontinued. If requirements become $\leq$ 10 cm of water at any time during the first 5 days after randomization, HBO2 treatments may be resumed. Daily chest radiography is performed, and if there are changes suggesting O2 toxicity, treatment is temporarily discontinued until the chest x-ray improves or it is greater than 5 days after randomization.

3.10.5 Management of the Severe TBI Subject in the HBO2 Chamber
3.10.5.1 Monoplace Chamber
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The Ohmeda volume monitor 5410/5420 is the device recommended and will be provided which will measure and monitor subject volumes and respiratory rates. There are alarms for high and low minute ventilation, and apnea after 20 seconds. The monitor is only to be operated by battery (DC) power and never by the AC/DC adapter. The Ohmeda monitor is never to be placed inside the monoplace chamber. Only the sensor clip goes inside the chamber connected to the subject's circuit on the exhalation side. The sensor clip has a power rating range of 0.0013 watts to 0.0015 watts. High and low alarms should be set approximately 10-15% below set Vt for low minute ventilation and 10-15% above set Vt for high minute ventilation. The apnea alarm is preset to alarm after 20 seconds of not sensing any volumes. The Magellan ventilator requires a constant watch and monitoring of the ventilated subject's Vt, RR, PIPs, and I:E ratio and the subject's chest movement and color during compression and decompression. Arterial gasses (ABG) can be obtained pre & post HBO2 treatment and are especially important in subjects with borderline pulmonary function (Weaver 1994). For patients assigned to the NBH only arm, ABG should be obtained pre-NBH treatment. Treatment should be held if PF ratio is <200, unless the clinical team deems it safe to proceed with NBH treatment. If vent settings and pulmonary status are optimized and the PF ratio improves, the study team may proceed with NBH treatment.

3.10.8 Chamber and Subject Log (Dive Log)
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Chamber and Subject logs should not be completed for participants assigned to the NBH only group.

Important EFIC Reminders!

- If no LAR is found within 6 hours of patient ED arrival, the patient can be enrolled under EFIC.
- No EFIC prior to 6 hours!
- ICL CRF (Form 211) - Document steps taken to identify the patient and find the LAR:
    - The first attempt on the log should always capture what is known about the patient ID and family status at time of arrival.
    - Subsequent hourly attempts in the first six hours prior to an EFIC enrollment, should be captured on the CRF and use available resources (social work, waiting room, treating team, patient bedside, etc.) until randomization.
    - For an EFIC enrollment, the attempt logged minutes prior to randomization should reflect what is known about family/LAR status at that time.
    - Finally, ongoing attempts should be captured no less than daily (as appropriate) until a consent determination is made by an LAR or the participant.
    - The ICL-CRF should be started as soon as possible and should be saved and submitted on a rolling basis as new information is added until a final consent outcome has been reached.
- A consent determination should be obtained within 24hrs. Except in rare circumstances.
- For subjects who expire before LAR consent is obtained, the HOBIT Deceased Notification Letter (located in the appendix of the EFIC plan) should be sent.
- Similarly to the process for loss to follow-ups, when a consent determination of “obtained” or “refusal” is not obtained by six months. The study team will be asked to present the case to HOBIT Leadership and the best final consent outcome code will be discussed.

Important resources: HOBIT MOP, Section 5, AND CRF Completion Guidelines, Form 211.

HOBIT Trial Contacts: hobit-milestone@umich.edu | hobittrial.org
Emergency 24-Hour Study Hotline: 1-833-HOBIT-PI (833-462-4874)