Hyperbaric Oxygen in Brain Injury Treatment Trial

HOBIT NEWSLETTER

HO$_2$BIT

October 15, 2021

Kudos.....

- Great job Iowa and Kentucky for each having a recent HOBIT enrollment
    - Iowa and Kentucky also enrolled these participants in BioHOBIT!
- We welcome our new site, St. Mary's Medical Center in West Palm Beach, Florida
    - Congratulations for completing their simulation video!

Upcoming Meetings

SIREN Journal Club
October 20, 2021 @ 1pm ET

SIREN Steering Committee
October 27, 2021 @ 12pm ET

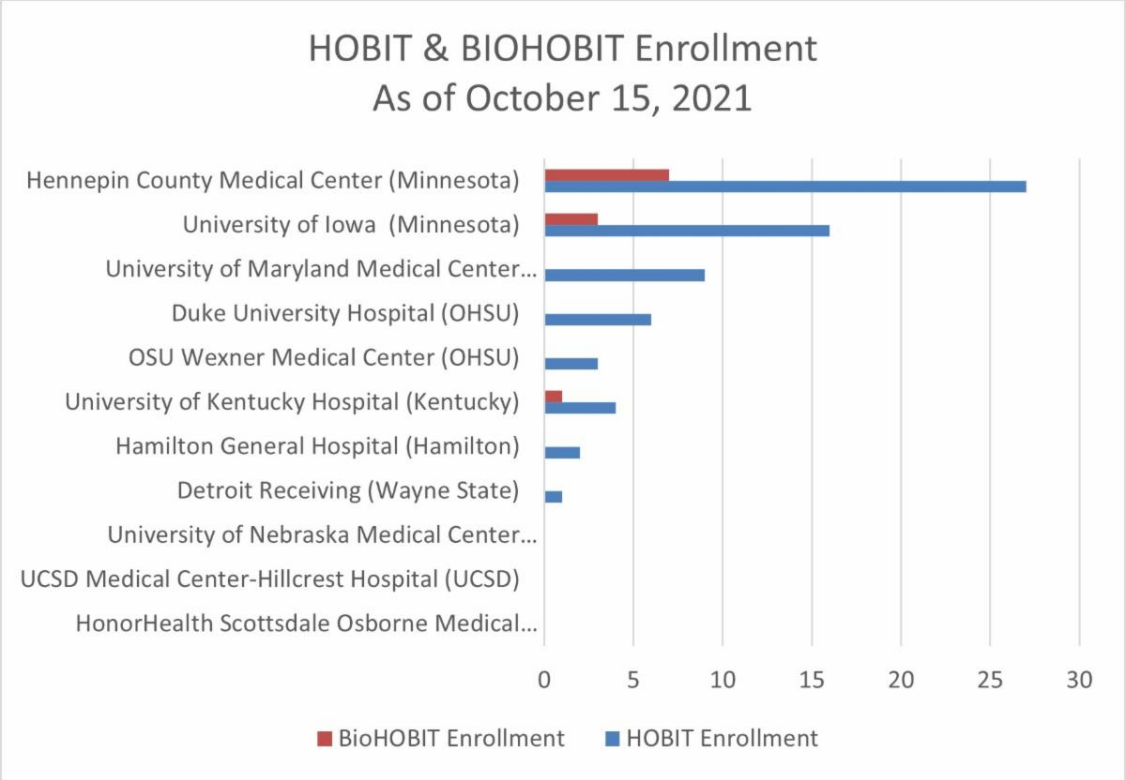
SIREN Study Coordinator Call
November 2, 2021 @ 1pm ET

HOBIT Virtual Investigators Meeting
November 11 @ 3pm ET and
November 12 @ 10 am ET

Enrollment Update

HOBIT: 68
BioHOBIT: 11

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



Please continue to screen diligently and enter screen failures in WebDCU

Neuroimaging is Live

Please review the following information about the WebDCU Database Change & the Neuroimaging portion of the HOBIT study.

Changes:

The new imaging form F254 has replaced the old imaging F271 and F272.

Transmission of all HOBIT imaging will be uploaded utilizing the secure IBM Aspera® web-based platform within WebDCU going forward.

Documents & Resources:

24/7 access the CRFs within WebDCU.

- **Click [Project Setup] -> [CRF Collection Schedule] -> Click on the Adobe PDF of the CRF you would like to download**

- **The Imaging Core Lab Manual is accessible within WebDCU under [Toolbox] or at siren.network in the HOBIT Toolbox**

Expectations:

Head CTs will be collected at baseline and post-intracranial monitor placement.

- **The baseline CT scan will be the first non-contrast head CT that is performed upon arrival at the enrolling hospital**
- **The post-intracranial monitor placement head CT scan will be performed shortly after ICP/PbtO2 monitors are placed**
- **Time and date must remain on the head CTs**
- **Ensure a zip file is uploaded for baseline and post monitor placement within each CRF**
- **Only include DICOM images; do not include reports or other file types**

Next Steps:

Please start requesting and uploading your HOBIT images.
In the next weeks Peyton Kline will schedule a check in meeting with each site.

If you have any questions or concerns, please don't hesitate to reach out to:

Peyton Kline, BSPH, CCRP
Data Coordination Unit
Medical University of South Carolina
843-876-1105

CLINICAL UPDATES

- We are aware that occasionally there are subjects who meet the criteria for enrollment in HOBIT however, the neurosurgery team is unwilling to place an ICP monitor because they deem it unwarranted clinically. Going forward, we will consider the enrollment of such subjects on a case-by-case basis. If you think you are going to miss a potential subject because the neurosurgery team does not think that ICP monitoring is warranted clinically, please call the PI HOTLINE (833-HOBIT-PI (833-462-4874)) to discuss further. Let us know if you have questions

- For patients receiving NBH treatment, use a timer to ensure that subjects don't get more than 3 hours of NBH treatment. Contact the CCC if you need a timer.

MOP Updates

HOBIT Manual of Procedures

In Section 3.2 Eligibility Criteria of the MOP we have provided additional guidance on determining the age eligibility criterion in the absence of confirmatory information. The changes have been highlighted in yellow.

The metric used to determine the age eligibility criterion is demographic history. Demographic history of age should usually be determined by past medical records (e.g., from prior hospitalization, outpatient encounters), other identification (such as driver's license or school or alternative ID), or from a family member or other person (to whom the patient is known) who can verify age. In the absence of confirmatory information, demographic history may also be clinically determined. In children or older adults in whom age is not clinically evident, determination of eligibility requires documentation or other confirmatory information. Age of minors is not intended to be estimated by height or weight, or by Tanner grade in this trial.

In Section 3.7.1 of the MOP we have also provided additional guidance on our new procedure for considering the enrollment of subjects in cases where the treating neurosurgery team deems ICP monitoring clinically unwarranted. The changes have been highlighted in yellow.

ICP monitor placement in this trial should be for clinical indications only and not solely for research purposes. Therefore, if the clinical team including the treating neurosurgeon deems ICP monitor placement in a potential HOBIT subject unnecessary, that potential subject may still be enrolled in the trial **ONLY** after **a consultation with and approval by one of the trial PIs via the HOBIT PI Hotline**. Patients who may be considered for enrollment in HOBIT without ICP monitoring if the treating neurosurgeon feels ICP monitoring is not indicated on clinical grounds alone and patient also meet the following criteria: (1) GCS 7 or 8 (2) Ventricles and cisterns are open on CT and no midline shift; (3) adequate respiratory monitoring in the HBO chamber. In addition, patients who are post-decompressive craniectomy may also be considered for enrollment without ICP monitoring.

If a subject is enrolled without ICP monitoring make sure you enter that in the ISSUES TABLE as a protocol deviation. As usual, if you don't think a patient's GCS of 7-8 is from TBI, don't enroll that patient. Reassesses the need for ICP monitoring before every dive.

CRF Completion Guidelines Updated

October 15, 2021

HOBIT Case Report Form Completion Guidelines

The guideline changes are highlighted in yellow.

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