



March 25, 2022

St. Mary's Medical Center is Released to Enroll!



UPCOMING MEETINGS



SIREN Study Coordinator Call

Tuesday, April 5, 2022 1:00pm ET

HOBIT CQIP

Monday, April 11, 2022 1:00pm ET

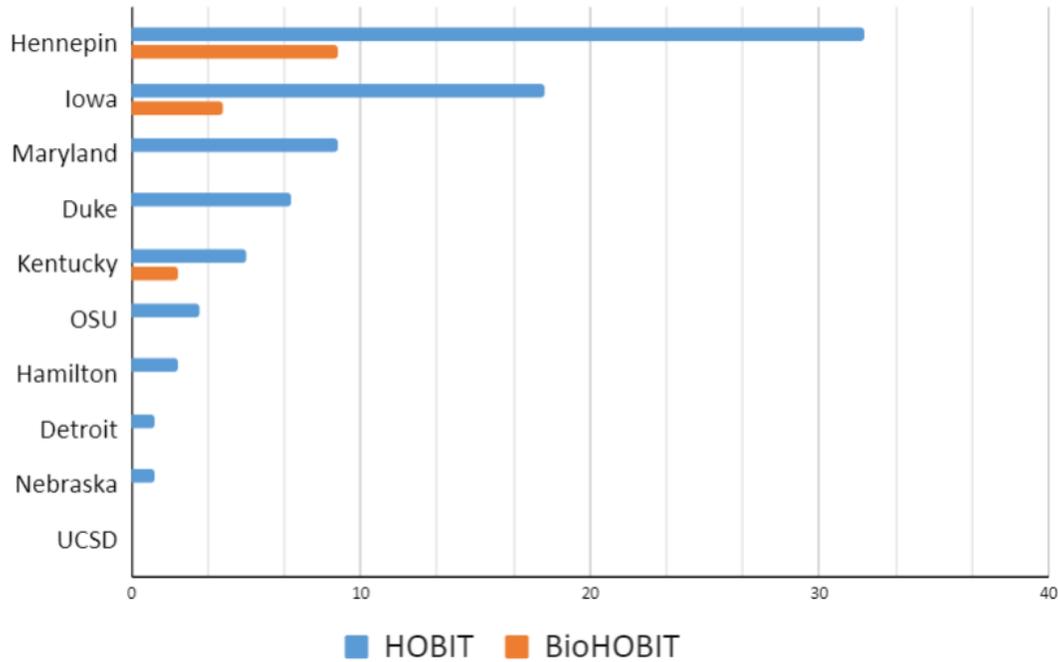
SIREN Steering Committee

Wednesday, April 27, 2021 12:00pm ET

ENROLLMENT

HOBIT: 78 BioHOBIT: 15

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



Please continue to screen diligently and enter screen failures in WebDCU

HOBIT UPDATES & RESOURCES

MOP Updates

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Timing of HBO dives

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

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Template for Death from TBI

The subject is a {age, gender} who was randomized into the {treatment arm} on {date} and completed {number} treatments on {date}. The subject's GCS score at the time of randomization was {X}.

Add any pertinent information such as family care conferences, subject/family wishes, treatment team's view of TBI severity, comfort care/extubation. The subject died on {date}. The last recorded GCS score at withdrawal from life support was {X}.

In Q011, can add any relevant CT/MRI data.

*** Of note as in MOP – if GCS score at time of withdrawal of life support is 2 points or greater than at the time of randomization, the adverse event name is "Withdrawal from life support," otherwise the adverse event name is "Neurological deterioration."

Reminder: Monthly Follow-up Interview

The site study coordinator will hold monthly follow-up phone calls with enrolled subjects/caretaker during their time of enrollment for the first 6 months post-randomization. These calls are essential to maintaining contact with subjects/caretaker and decreasing the likelihood of "loss to follow-up" at the 6-month visit.

A log of all calls is documented in the Monthly Follow-up Log in WebDCU under the Study Progress tab.

During these calls, study coordinators should inquire about the occurrence of any adverse events and ensure that subject/caretaker's contact information is accurate and not expected to change in the coming month.

If the subject has experienced any adverse events since last contact, the coordinator must complete CRF 104 Adverse Event. The AE should be reported in WebDCU under the most recent visit (Hospital Discharge, Day 30, etc.).

If the subject or relative/caregiver/friend is unable to be contacted, the attempt should be noted on the Monthly Follow-up Log.

Contact with subjects should occur whether the subject is an in-patient or is post-discharge.

Recently Entered Screen Failures "Reasons for Exclusion" Explained

Calling the HOBIT PI Hotline (24/7) is always recommended if your study team is unsure about a potential subject's inclusion/exclusion status.

Here are a few examples of "reasons for exclusion" that were recently entered in the screening logs that may not fully qualify as "reasons for exclusion"

- Untreated pneumothorax: Depending on the size of the pneumothorax and the patient's overall respiratory status, a patient with untreated pneumothorax may still qualify for inclusion and HBO treatment. Call the PI hotline to discuss if you are considering enrolling such a patient.
- Cervical spine fracture: Patients with cervical spine fractures may be enrolled if the fracture is not deemed unstable and there is no spinal cord involvement. Call the PI hotline to discuss if you have questions.
- Persons in police custody: While prisoners or wards of state are excluded from the trial, persons who present in police custody and may be arrested after discharge are not automatically excluded, so long as they are not currently a prisoner or ward of state.
- Homelessness. Homelessness alone is not an exclusion. Some homeless persons are chronically homeless, whereas others maybe transitional or episodic. Some may have very reliable contact/LAR information etc. Therefore, it is okay to enroll a homeless person if the study team is fairly certain that the chances that they will be lost to follow up are low.

WebDCU Reminder

While working in WebDCU, please remember to **not** have more than one tab open. Having two WebDCU tabs open at the same time can cause major issues within the system if you were to save or submit a form on one of those tabs.

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