Hyperbaric Oxygen in Brain Injury Treatment Trial

HOBIT NEWSLETTER

HO$_2$BIT

February 4th, 2022

University of Kentucky Hospital

Enrolled the 1st HOBIT & BioHOBIT subject of 2022!

UPCOMING MEETINGS

SIREN Steering Committee
Wednesday, February 23, 2021 12:00pm ET

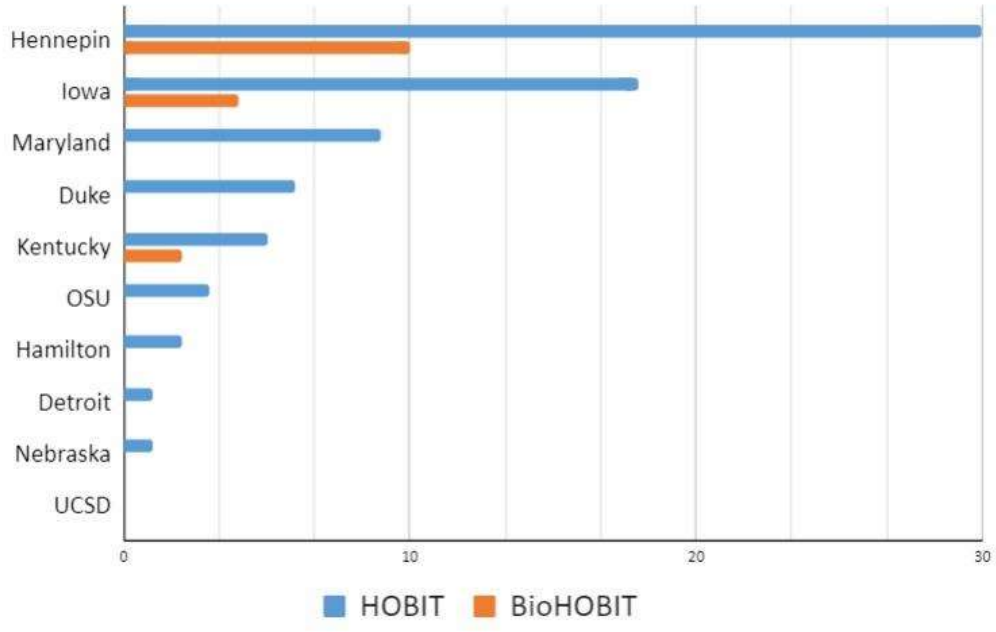
HOBIT CQIP
Monday, February 14, 2022 1:00pm ET

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

ENROLLMENT

HOBIT: 75 BioHOBIT: 16

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



Please continue to screen diligently and enter screen failures in WebDCU

HOBIT UPDATES & RESOURCES

HOBIT Continuing Review

The HOBIT Continuing Review is being reviewed by Advarra on Friday, February 4th, 2022. Shortly after we receive continuing approval, the letters will be available in WebDCU.

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FAQ:

What to do if a participant says they want to withdraw from the study

The goals in responding to this kind of inquiry are to make sure participants know and understand their options, that we respect the choice of the participant, and that we preserve the integrity of data collection as much as possible.

1) Do not pressure the participant (or LAR) to remain in the study. A research participant always has the right to withdraw from the study at any time and for any reason.

2) Often your site PI will be in the best position to discuss options, as well as the importance of participation. Ask if the participant (or LAR) would like to talk with the PI.

3) Inform the PI as soon as is practical either way.

4) Try to clarify what they want to stop. Often requests to withdraw from the study are just requests to withdraw from certain elements of the intervention, or to skip a blood draw or other assessment or visit. Participants may opt out of most elements without withdrawing from the study.

a. Ask specifically if they would like to completely withdraw from the study or are reticent about a particular **part** of the study (the outcome evaluation, monthly phone calls, for example).
b. **Study personnel** should be aware that we can usually forgo the more burdensome portions of the study.
c. If they are amenable to a short phone call in 6 months to see how they are doing, let them know that you can speak with the LAR, a friend or relative, or them. The study's primary goal is to obtain the GOSE at the 6-month post-injury point.
d. Ask "even If you want to stop everything else, may we look at your medical record while you are in the hospital?" Even if they only agree to continued chart review, this should not be considered a withdrawal of consent for participation.

5) If they want no further contact, honor their wishes and thank them. Document withdrawal of consent on the end-of-study case report form.

As you talk with the participant/family it may become clear that they do not want to participate under any circumstance. In this case it is certainly their right to withdraw and no further contact should be made by study staff. Thank them for their participation.

Reminder! Enrolling Without ICP Monitor

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!

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