

HYPERBARIC OXYGEN BRAIN INJURY TREATMENT TRIAL: A MULTICENTER PHASE II ADAPTIVE CLINICAL TRIAL

HOBIT Huddle
Monday, November 10th 2025

1:00pm - 2 pm ET

 HO₂BIT



Agenda

Monday, November 10th, 2025 1:00pm - 2:00pm ET			
Start	End	Item	Presenter
1:00pm	1:05pm	Welcome	Gaylan Rockswold
1:05pm	1:20pm	Patient Story from HCMC	Beth Nierengarten
1:20pm	1:30pm	Renewal and Contract Updates	Bill Barsan, Valerie Stevenson
1:30pm	1:40pm	Milestones and Expectations	Fred Korley
1:40pm	1:45pm	Chamber and Subject Log Rev. 10	Bill Gossett
1:45pm	1:50pm	HBO Treatment Approach	Chris Logue
1:50pm	2:00pm	Questions and Adjourn	Gaylan Rockswold

Welcome

Gaylan Rockswold, MD



Patient Story from HCMC

Beth Nierengarten



Case Presentation

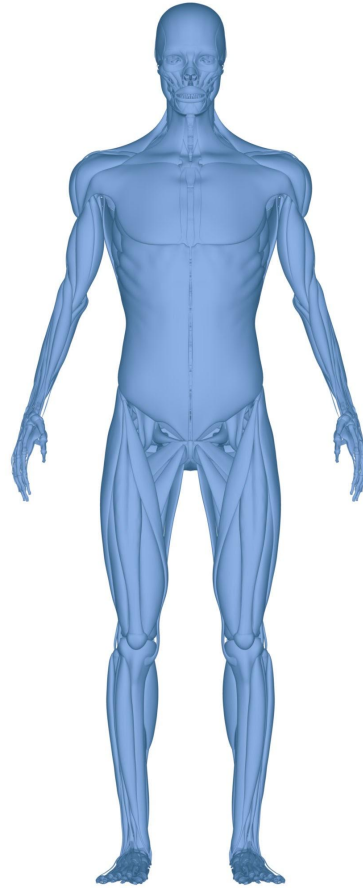
39M transported by helicopter to ED in Sept 2023 with polytrauma after a motorcycle accident where he lost control and ran off the road going highway speeds.

At the scene Pt with AMS. Obvious deformities noted to multiple extremities and face. Pt intubated in the field. Became hypotensive. TXA and 2 units of PRBCs given prior to arrival in the ED.

Head: SDH R frontal lobe, SAH L Temporal lobe, epidural hematoma with midline shift, L frontal lobe intraparenchymal hematoma/contusions, L orbital fracture with hematoma, multiple fracture to nasal bones and maxillary sinuses and pneumocephalus

Emergent hemicraniectomy with EVD placement, arterial bleed to middle meningeal artery requiring endovascular embolization

Abd/Pelvis: L adrenal hematoma/hemorrhage, L kidney acute arterial injury, Liver laceration, Fx L proximal fibular head, avulsion to L iliac crest,



Neck: Fx of the right occipital condyle and slight asymmetry at this joint space.

Chest: L pneumo/hemothorax, L pulmonary contusions, L clavicular fx, multiple bilateral rib fxs

Intubated with chest tube placement in ED

Extremities: Fx R medial tibial plateau, multiple R ulnar fxs, multiple R radial fx, L humerus Fx

Timeline

ED 9/9/2023

1439: Patient arrived to ED

Ongoing resuscitation efforts including MTP, Chest tube placement, Central line and Art line placement

Multiple specialist consults

Procedures 9/9/2023

1705: To OR with NSG for hemicraniectomy and EVD placement

1934: To IR for MMA embolization

Family present at bedside

SICU 9/9 - 9/10/2023

2125: Pt arrives in SICU post procedure

0057: GCS of 6 off sedation

Ongoing screening of patient for HOBIT and introduction of study to family. LAR identified.

HOBIT 9/10/2023

0115: Consent signed

0136: Patient randomized

Patient treated per protocol through day 6.

Multiple surgeries. Several episodes of Dec P/F ratio, ICPs well controlled

Timeline

Acute Hospitalization

27 days in SICU

Multiple surgical procedures with NSG, Ortho and ENT

10/5/2023

Discharged to VA inpatient acute rehab unit

Day 30 10/13/2023

Pt remains in ARU requiring 24/7 care

**10/17 to 11/28/2023
Re-admitted to HCMC**

New intracerebral hematoma, IVH and pneumocephalus & CSF leak

Multiple procedures:
Craniectomy, EVD, VP shunt

Day 90 12/8/2023

Pt remains in ARU requiring 24/7 care

**12/14 to 12/22/2023
second HCMC re-admission**

CSF leak noted at scalp incision

To OR for debridement and complex surgical closure with plastic surgery

Day 180 3/12/2024

Pt home, not fully independent but can be left alone for 24 hrs

Back to work as a mechanic part time w/ accommodations

Recently cleared to drive

“I want to say thank you again for allowing my dad to participate in this study. I'm confident that it changed his life - all of our lives.”

-Daughter of Participant 1266

Renewal and Contract Updates

Bill Barsan, Valerie Stevenson



Milestones and Expectations

Fred Korley

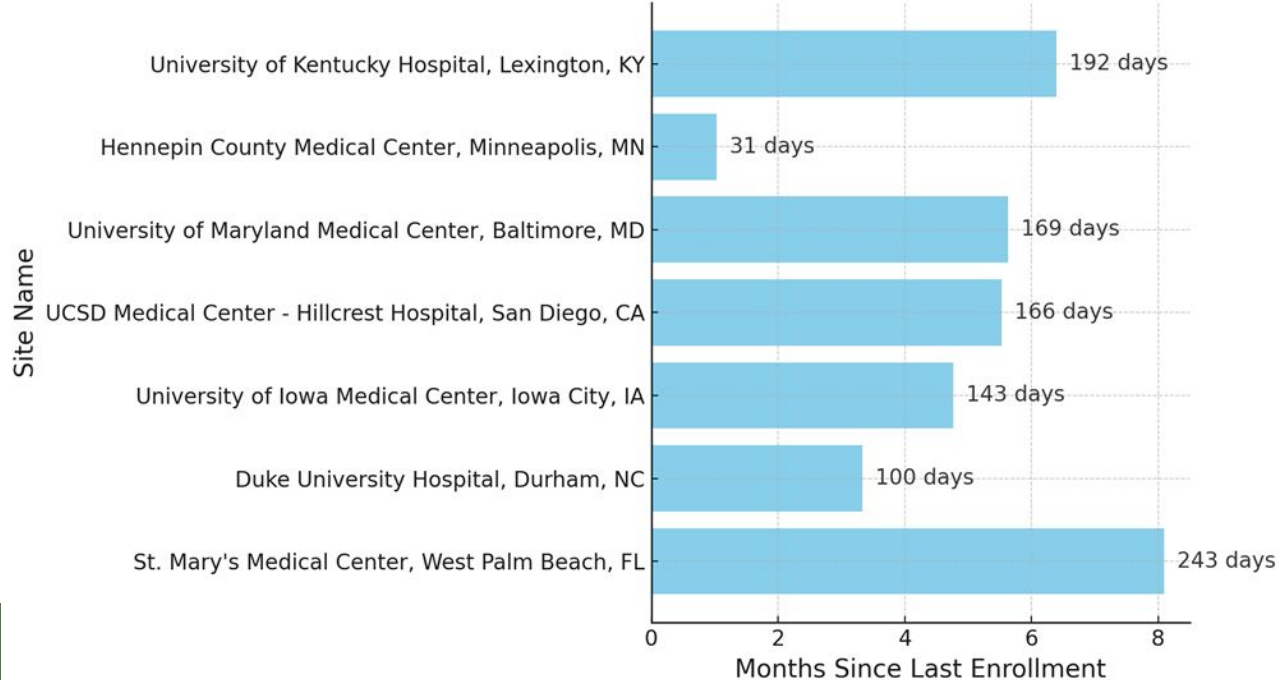


HOBIT Year 6 Milestones

- Hold annual investigator meeting.
- Obtain DSMB recommendation, with concurrence by NINDS, that the study continue to enroll participants following review of the third pre-planned interim analysis (at N=156).
- Reach a total target enrollment of 165 participants.
- Annual submission of data against initial FITBIR Form structure for data collected using GUIDs (Global Unique Identifiers).

Time since last enrollment

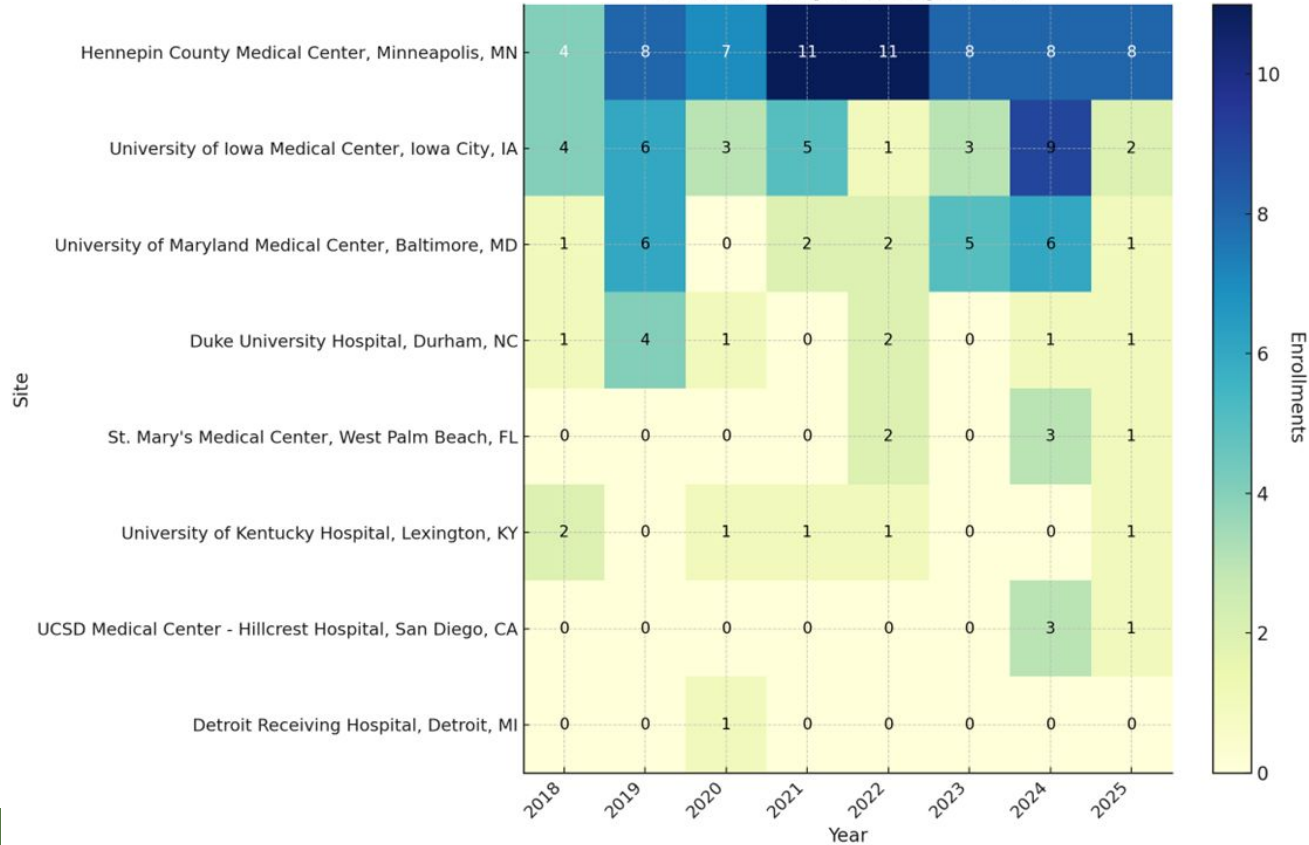
Months Since Last Enrollment by Site (Excluding Detroit)



Note: Detroit Receiving Hospital has not enrolled in 2131 days.



Enrollment per Site per Year



Enrollments



Chamber and Subject Log Rev. 10

Bill Gossett



HOBIT Trial – Chamber and Subject Log (Rev. 10)

Instructions:

1. **NEWEST REVISION:** Please reference the HOBIT Workbench for the latest Revision: [Chamber and Subject Log](#)
2. **UPLOADING FORM TO WEBDCU:** Please upload as PDF to WebDCU and only upload page one of [this form](#), not the “Instructions” on page two.
3. **ADDITIONAL COMMENTS:** If additional space is needed for comments, use a separate page and upload to WebDCU as a PDF, along with the Chamber and Subject Log.
4. **PERSON RECORDING:** If possible have only one individual complete this form.
5. **REAL-TIME DATA:** It is important to accurately record treatment “dive” times, and all required subject data in the actual clock time.
6. **RECORDING PERIOD OF 100% FIO₂:** Please record when the subject is switched from 100% FIO₂ to the subject’s baseline (ICU) FIO₂. See lower box on Log.
7. **IF RANDOMIZED TO HBO₂ + NBH:** No NBH treatment should be given if the HBO₂ treatment is **mised/not initiated**. If the HBO₂ treatment is initiated and subsequently aborted Saved to V: Drive treatment should still follow the aborted HBO₂ treatment.
8. **THE LOWER BOX:** The lower box includes check boxes for ICP, CPP and MAP parameters. Please note and record a brief comment of the situation or action taken in this box.
9. **SIGNING FORM:** The person filling out the Chamber and Subject Log should sign their name and provide their title at the bottom of the form.
10. **TOP GRAY BOX:** An ABG is to be drawn after the subject has been placed on the hyperbaric ventilator **and is still on the baseline (ICU) FIO₂**. A PF ratio of 200 or more (calculated from this ABG) is required prior to initiating each HBO Treatment without a Hotline call.
11. **SECOND GRAY BOX:** If the **initial** ABG results require changes to the HBO ventilator settings, then a **repeat** ABG is required on the **new** ventilator settings. Record both the new HBO vent changes along with the ABG results and record the newly calculated PF ratio in the second gray box.



HBO Treatment Approach

Chris Logue



Questions & Adjourn

Gaylan Rockswold

