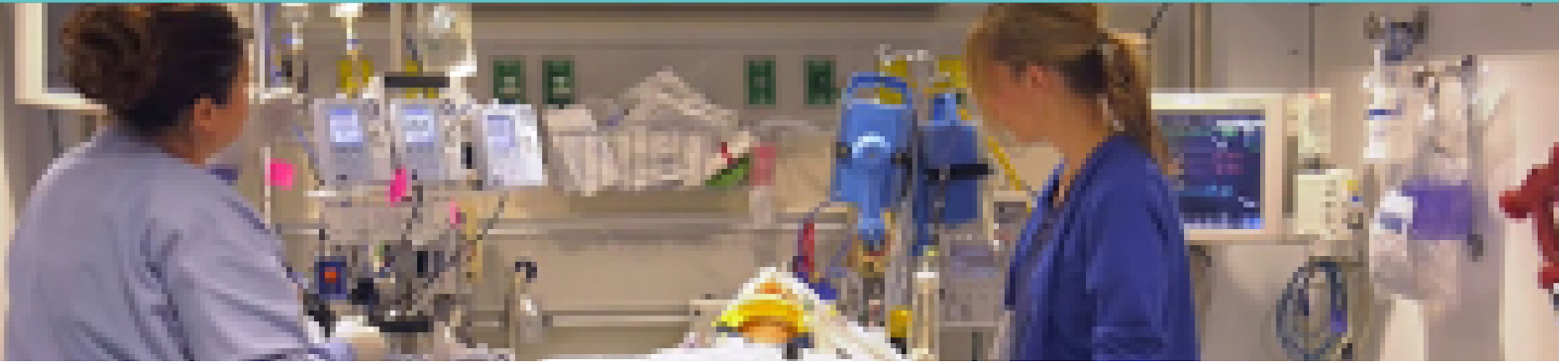


HOBIT TRIAL

Seeking Multiplace Critical Care Sites



Hyperbaric Oxygen Brain Injury Treatment Trial (HOBIT) is a Phase II, multicenter, randomized, single-blinded, adaptive clinical trial of HBO treatment delivered very early after injury in patients with severe traumatic brain injury (TBI). It is designed to provide important data about dose selection to plan a definitive phase III efficacy trial.

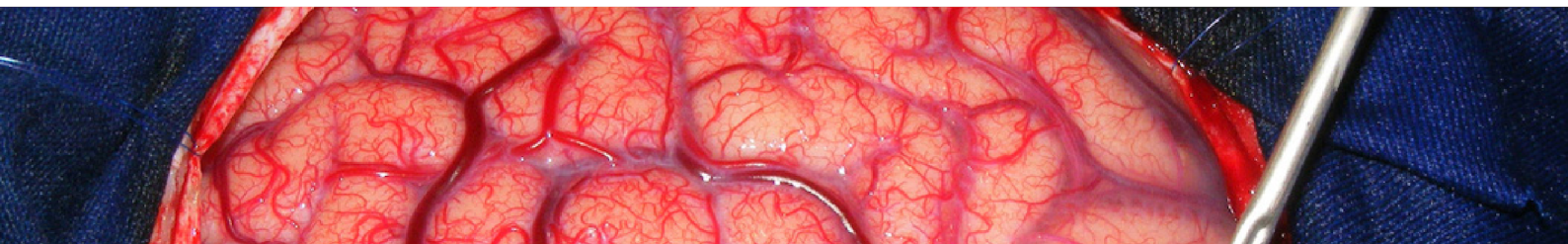
HOBIT is supported by the SIREN Network and funded by the National Institutes of Neurologic Disease and Stroke.

Registered with [ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT02407028): [NCT02407028](https://clinicaltrials.gov/ct2/show/study/NCT02407028) NIH Project Number: [1U01NS095926-01A1](https://clinicaltrials.gov/ct2/show/study/NCT02407028)

Current Trial Sites

- Duke Health
- University of Kentucky
- University of Nebraska
- St. Mary's MC, West Palm Beach
- Detroit Receiving
- Hennepin HealthCare (HCMC)
- University Calif. San Diego
- University of Iowa
- University of Maryland

RATIONALE: Despite an improved understanding of the condition, severe traumatic brain injury victims remain at high risk of poor outcomes and mortality. Prior clinical investigations indicate that hyperbaric oxygen (HBO2) can have a positive impact on reducing brain injury and improving outcomes in severe TBI.



Site Requirements:

- Trauma Center with TBI expertise
- Multiplace HBO critical care experience
- International sites considered

Reimbursement:

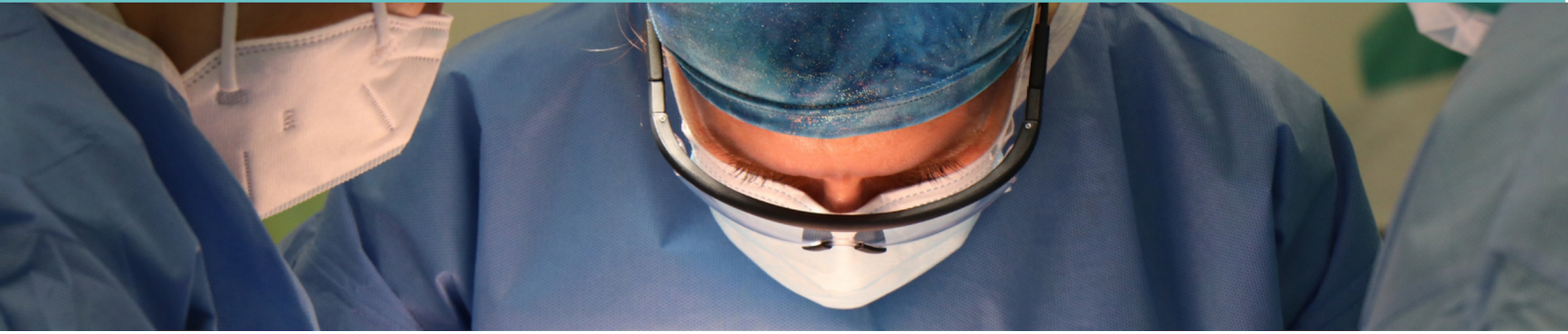
- Up to \$32,500 per subject
- Up to \$12,500 for Control and NBH Arms
- Up to \$4,800 for BioHOBIT
- \$30,000 for EFIC Start-up

Trial Features:

- GCS 3-8; Comatose on full life support
- 3-HBO Arms at 1.5, 2.0, 2.5 ATA
- 3-HBO Arms plus NBH x 3 hours after HBO Treatment
- 1-NBH only Arm x 4.5 hours (NBH = 100% Oxygen 1 ATA)
- 1-Control Arm
- All Treatment Arms are Q-12 for 5 Days

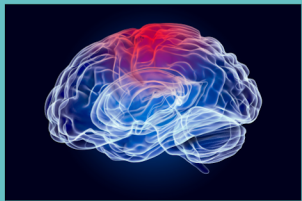
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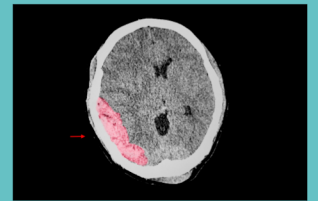


CURRENT PROGRESS: The first HOBIT subject was enrolled in 2018. As of January 2023, there have been a total of 94 subjects enrolled out of the projected 200, and 480 HBO treatments have been delivered.

There are currently nine enrolling sites and the HOBIT Trail is actively seeking additional Level 1 Trauma sites that provide multiplace hyperbaric critical care services. The trial is open to both US and international sites.



Facts About TBI



Annually, about 2.5 million people sustain a traumatic brain injury, which can lead to disabilities and death. In 2020 there were 64,362 TBI-related deaths including 2,774 among children.

The costs to society for care and lost productivity due to brain trauma are enormous and estimated at \$76.5 billion annually. But the financial cost is only part of the burden.

In the U.S., over 5 million men, women, and children live with a TBI-related disability. The long-term impairments and disabilities associated with TBI are grave and the full human cost is incalculable. Yet because these disabilities are not readily apparent to the public—unlike a broken leg, for example—TBI is referred to as the invisible epidemic. These disabilities, arising from cognitive, emotional, sensory, and motor impairments, often permanently alter a person's vocational aspirations and have profound effects on social and family relationships.

Reference: https://www.cdc.gov/traumaticbraininjury/pdf/TBI-Surveillance-Report-Final_508.pdf
https://www.cdc.gov/traumaticbraininjury/get_the_facts.html
<https://www.braintrauma.org/faq>



Clinical research, such as HOBIT, offers hope to TBI victims and their families!
Be a part of it.