Hyperbaric Oxygen Brain Injury Treatment (HOBIT) Trial

Community Consultation

Local Study Team:

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NIH SIREN Emergency Trials Network

The HO$_2$BIT Study

Principal Investigator

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Topics for today

- Traumatic brain injury (TBI)
- The HOBIT study
- Emergency research and consent

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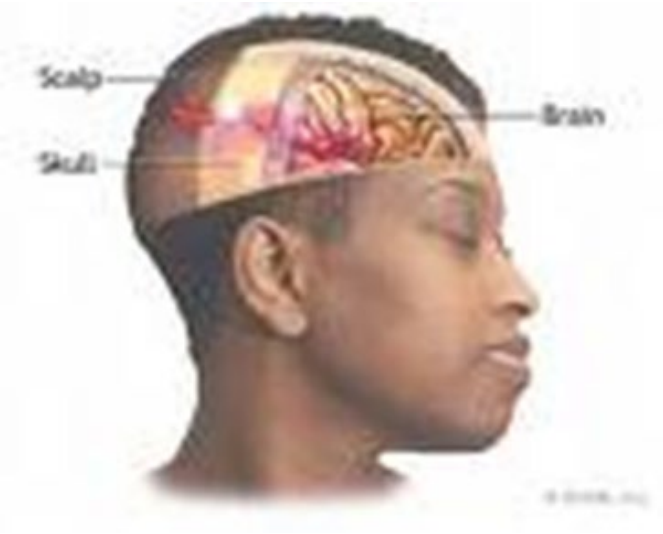
What is Traumatic Brain Injury (TBI)?

Traumatic Brain Injury is sudden damage to the brain caused by an outside force - such as a car crash, a fall, or something hitting the head.



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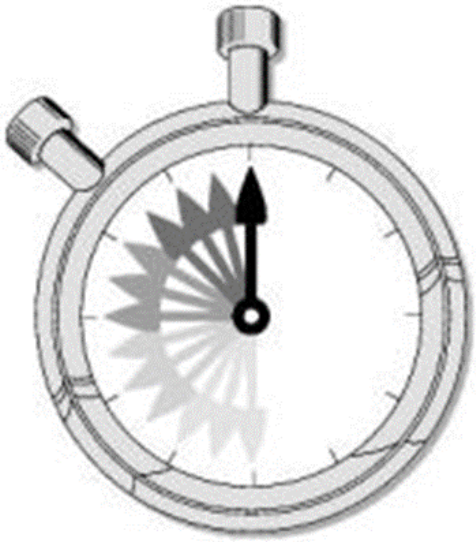
TBI is the leading cause of death in children and adults ages 1 to 44 years

- Every 15 seconds, someone in the US suffers a major TBI!
- Every 5 minutes, someone is forever disabled as a result of TBI.



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What problems does TBI cause?

Death

Coma

Inability to think clearly

Memory loss

Impaired balance and coordination

Inability to return to work

Inability to live independently

Does anyone here know someone who suffers from a brain injury?

Treatment of Severe TBI

- Ventilators
- Lots of tubes, lines, and monitors

- Goal directed care

- Maintain adequate blood flow to the brain
- Maintain adequate brain oxygen levels

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This study will identify the best way to deliver high dose oxygen under pressure (hyperbaric oxygen) so that severe TBI patients can recover with less disability.

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Have any of you been in a medical research study?

What was your experience like?

Who WILL be included in this study?

- Anybody who is 16 to 65 years old,
- has head injury,
- is unconscious,
- and study treatment can be started within 8 hours of arrival to study hospital

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Treatment

People who meet the entry criteria will be randomly entered, like flipping a coin, into one of the eight study groups:

- One group will receive the usual amount of oxygen.
- Another group will receive a high dose of oxygen that is not pressurized.
- The remaining six groups will receive a high dose of oxygen that is delivered for different amounts of time and with different amounts of pressure inside a hyperbaric chamber.

All participants will also receive standard of care treatment for their TBI.

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What else will happen in this study?

Participants in all study groups will:

- Receive usual treatment for TBI, no matter which group they are assigned.
- Have one teaspoon of blood taken at 10 different timepoints during the 6-month study period to monitor the severity of brain injury and response to treatment.
- Study treatments will be performed twice a day for 5 days.
- Be called at 30 & 90 days after injury to see how they are doing.
- Be asked to return to the clinic 6 months after their brain injury to conduct an interview to see how they are doing

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What are the possible risks?

Participation in this study carries the following risks which occur infrequently:

- Pneumonia or lung injury/infection
- Seizure
- Ear infection
- Complications of transport to and from chamber

Risks of participating in research include:

- Breaches of confidentiality

There may be unanticipated risks

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What are the possible benefits?

- Treatment of traumatic brain injury with hyperbaric oxygen (oxygen under pressure) may be more effective than the standard of care.

- Potential for benefit to future patients with traumatic brain injury from what is learned from this study.

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How are emergency studies different?

- In most studies, investigators explain what will happen, describe possible risks and possible benefits, answer questions, and then the eligible patients decides whether to participate. This process is called Informed Consent.
- In this emergency study, eligible patients are unconscious and cannot decide or communicate whether or not they wish to participate in a study. Family members may not be readily available to provide informed consent.

So how do we do emergency research?

Specific federal regulations allow an
Exception From Informed Consent for emergency research

EFIC is only allowed when**:**

- The condition being studied is life-threatening
- Getting consent is not possible due to time-sensitive intervention

Special requirements for EFIC

- Community consultation (why we are here)
- Public disclosure before and after the study
- Oversight during the study

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How does EFIC work in HOBIT

- If a family member or representative is available, they will decide for the patient
- If not, eligible patients will be started in the study without consent
- Family members or representatives are told about the study as soon as possible and asked whether participation can continue

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What if I don't want to be in the study?

- Ask us for a medical alert bracelet that says "HOBIT study declined" or add those words to your existing medical-alert notification.

- In the event you suffer a severe traumatic brain injury, you will not be enrolled in the study if you are wearing that medical alert notification when you arrive at the hospital.

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What do you think about HOBIT?

- We want to hear your thoughts.
- Tell us about your experiences.
- Do you think it is okay to do this study?

The study team and the research review board will consider your opinions before deciding if it is okay to do in our community.

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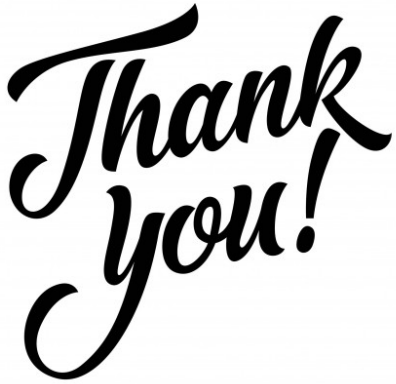
Questions?



If you have any questions, comment
concerns about the study, please speak with us now and/or contact us at:

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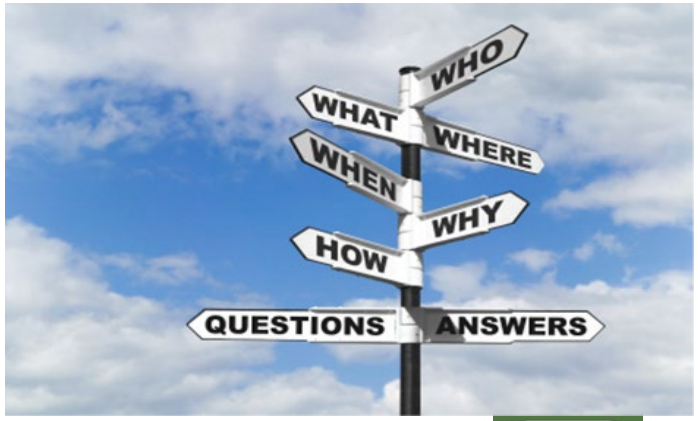

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hobittrial.org

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