

# HOBIT

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

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# Lessons Learned from ProTECT™

# ProTECT™ Trial and HOBIT Trial Comparison

- Both TBI Trials
- Both have limited time to enroll severely injured patients
  - Patients lack capacity to consent for themselves
- ProTECT was EFIC trial - HOBIT requires prospective LAR consent
- Study protocols may change the usual routine care.
- Data collection is more complex than other studies.

# Prioritizing Coordinator Tasks when you get the call for an enrollment....

- Get enough information on your way to hospital or ED
  - Location of patient in the hospital now or expected time of arrival?
  - Time of injury (how much time is left to consent?)
  - Is family present or en route? What is their ETA?

# Call back Investigator/Research Team

- Remind them of protocol
  - Order pregnancy test (if female) – may save 30 minutes or more of time
  - Order ETOH level
  - Ask additional eligibility questions that can be overlooked
  - Is patient expected to need immediate surgical intervention?
- Ask: Has anyone spoken to family yet?

# Use ED resources: Research Associates (RA)

- Call the RA to inform them of potential enrollment and ask them to track the lab results, EMS run sheets and whereabouts of the potential subject.
- Ask RA to call you when patient or family arrives or if anything changes.
- RA may be able to hand ED team the inclusion/exclusion criteria if Neurosurgery/Trauma has not arrived yet. Make sure nothing is ordered that would lead to an exclusion.
- RA can track new information that may change the known time of injury (enrollment window).

# Coordinator Role

- Watch the clock. Establish time of injury as time of enrollment window.
  - Inform the team of time frame.
  - Be on the lookout for new information from source documents and potential conflicting information. Start a note to file if discrepancies are found. Explain who provided the information and when you or the team learned of it.
- Get help to track family arrival for obtaining consent.
  - Enlist investigator to speak to family first
  - PI/ Co I explains research participation and introduces coordinator to more fully explain the study and obtain written consent.

# Time saver tips

If there is any “down time” while waiting for family, investigator, lab results, imaging, etc...

- BEGIN entering information on paper eligibility forms for WEBDCU.
- Get these ready so that once consent is obtained – you will have all the information ready to enter.

Option: work with your fellow coordinators to search EMR for eligibility criteria. They can be remotely working on forms while you are talking with family.

Do not enter information into WEBDCU until you have consent.



# Once consent is obtained....

- Notify team immediately of Randomization assignment.

# Ancillary Notifications: Plan Ahead

- HBO personnel
- Respiratory Therapy
- Nursing/ICU
  
- Each team will likely need to be reminded of their role/responsibilities. Coordinators are important Protocol “cops”.
- Be physically present when subjects are enrolled to solve issues/run interference.
- ICU: stay with subject at least until you have had time to provide protocol info to Staff Nurse, oversee EPIC order entry and HBO treatment.

# Notifying Ancillary Research team partners: HBO unit notification

- Each site will determine when HBO wants to be notified of a potential enrollment.
- Considerations:
  - Costs to activate HBO personnel after hours if randomized to non HBO arm.
  - Time it takes for HBO personnel to arrive and be ready for subject.
  - Daytime: heads up may be useful if schedule needs to be juggled to accommodate subject urgently

# Nursing and Protocol Compliance

- Nurses will “buy in” to the study if coordinator shows effort to work with them.
- Nurses instinctively “protect” their patients and appreciate learning basic information about the study.
- Research will add to the RN workload. Be sensitive to their routine and availability.
- Protocol needs nurses to record ICP’s hourly in EMR: this may be more data than they are used to...
- HBO schedules and MRI’s per protocol – may be stressful for RN.

# Coordinators: Create your tag team

- Be present for as many HBO treatments as possible and checking overall status of subject. Answer questions as they arise.
  - Remotely monitor schedule using EPIC.
  - Call unit as needed to check on schedule changes, etc.
  - Watch that orders are being entered at appropriate time interval.
  - Watch for AE and SAE and promptly report them
- Enter data daily for patients.
- Assign one coordinator if possible to track all data and enter into WebDCU.
- Be visibly present each day – shows your commitment to the study. You can more easily correct issues as they arise. **AVOID Protocol DEVIATIONS!**

# Data Entry

- HOBIT has taken great care to keep data collection streamlined. However there are some critical data points that are collected hourly.
- This data will help to make sure these patients are being followed per protocol.
- Daily data entry help you detect management issues in “real time” and address them with your team.

# Show your appreciation to staff: early and often

- While staff may have buy in and loyalties to the medical staff (PI and Co I), they may still feel overworked due to the protocol demands.
- Keep them updated on subject progress.
- Verbally show your appreciation on a daily basis.
- Write notes to their supervisors and note staff dedication, extra effort, etc. to go above and beyond.
- Consider small gift cards for staff caring for patients (\$5/day coffee card).
- Consider \$5 gift cards if staff complete protocol training (LMS module).
- Chocolate works wonders too.

# Questions?

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