HOBIT Inclusions/Exclusions







Inclusions

- Age 16-65 years
- Severe TBI, defined as iGCS of 3 to 8 (if intubated, motor score<6) in the absence of paralytic medication
- For patients with a GCS of 7 or 8 or motor score = 5, Marshall computerized tomography (CT) score >1
- For patients with an alcohol level >200 mg/dl, Marshall computerized tomography (CT) score >1
- For patients <u>not</u> requiring a craniotomy/craniectomy or any other major surgical procedure, the first hyperbaric oxygen treatment can be initiated within 8 hours of <u>admission</u> to enrolling hospital
- For patients requiring a craniotomy/craniectomy or major surgical procedure, the first hyperbaric oxygen treatment can be initiated within 14 hours of <u>admission</u> to enrolling hospital
- Written, informed consent from LAR





Exclusions

- Can't receive HBO2 treatment within 24 hours
 - Unlikely to benefit after 24 hours
- GCS of 3 with non reactive mid position pupils without paralytics
 - Avoid futile patients
- Penetrating head injury
 - Avoid enrolling patients with poor prognosis
- Pregnant
 - Effect of HBO2 unknown on fetus; Must have urine or pregnancy test
- Prisoner or ward of the state



Exclusions

- Acute spinal cord injury with neurologic deficits
 - Contraindication to transport; treatment confounder
- Contraindication to ICP monitor placement
 - ICP monitoring necessary to manage patient
- Pulmonary dysfunction
 - P/F ratio must be < 200; PEEP < 10
 - Risk of worsening lung injury from oxygen toxicity
- Coma suspected to be due to primarily non-TBI cause
 - TBI not primary explanation for altered mental status
- Non-survivable injury
 - Withdrawal of care, hospice, DNR, aggressive treatment not indicated



Exclusions

- Concern for inability to follow-up at 6 months
 - Residency in foreign country; high likelihood of lost to follow up at 6 months
- Inability to perform activities of daily living (ADL) without assistance prior to injury
 - Difficulties with ascertaining outcomes
- Implantable device/drug that is incompatible with HBO treatment
 - Refer to manual of procedures for list of potential devices
 - Device may malfunction in hyperbaric chamber







Investigator Meeting February 2018

