

Brain Oxygen Optimization in Severe TBI, Phase 3

Status: RECRUITING

Eligibility Criteria

Age: 14 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Non-penetrating traumatic brain injury * Glasgow Coma Scale (GCS) 3-8 measured off paralytics * Glasgow Coma Scale motor score ≤ 6 if endotracheally intubated * Evidence of intracranial trauma on CT scan * Able to place intracranial probes and randomize within 6 hours of arrival at enrolling hospital * Able to place intracranial probes and randomize within 12 hours from injury * Age greater than or equal to 14 years

Exclusion Criteria:

* Non-survivable injury * Bilaterally absent pupillary response in the absence of paralytic medication * Contraindication to the placement of intracranial probes * Treatment of brain tissue oxygen values prior to randomization * Planned use of devices which may unblind treating physicians to brain tissue hypoxia * Systemic sepsis at screening * Refractory hypotension * Refractory systemic hypoxia * $\text{PaO}_2/\text{FiO}_2$ ratio ≤ 150 * Known pre-existing neurologic disease with confounding residual neurological deficits * Known inability to perform activities of daily living (ADL) without assistance prior to injury * Known active drug or alcohol dependence that, in the opinion of site investigator, would interfere with physiological response to brain tissue oxygen treatments * Pregnancy * Prisoner * On EFIC Opt-Out list as indicated by a bracelet or medical alert

Conditions & Interventions

Interventions:

OTHER: ICP + PbtO2 guided management strategy, OTHER: ICP guided management strategy

Conditions:

Brain Injuries, Traumatic

Keywords:

intracranial pressure, hypoxia, brain, critical care, emergency treatment, monitoring, physiologic

More Information

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Principal Investigator:

Phase: NA

IRB

Number:

System ID: NCT03754114

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