Title: ATO-06 - A Prospective Clinical Evaluation of Biomarkers of Traumatic Brain Injury (ALERT-TBI)

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Sponsor: Banyan Biomarkers, Inc.

Purpose of Research

The purpose of this study is to determine if a laboratory test can detect specific proteins in the blood from patients following a head and /or brain injury. Banyan Biomarkers, Inc is the company that is developing the laboratory test called the Banyan UCH-L1/GFAP Detection assay and it is experimental which means the (FDA), the Food and Drug administration has not approved this for use. This test will not be used to treat or diagnose the subject's condition, but will be used to test the subject's blood.

Inclusion Criteria

1. The subject has presented to a Health Care Facility (HCF) or Emergency Department (ED) with a suspected traumatically induced head injury, as a result of insult to the head from an external force. This includes self-reported or witnessed head injuries inflicted by blunt force, blast mechanism, and acceleration or deceleration events, including falls, assault, motor vehicle accident, sports injury, and explosion.
2. A Glasgow Coma Scale score of 9-15 at the time of Informed Consent.
3. Workup includes head Computerized Tomography (CT) scan, as part of clinical emergency care within 3 hours of presenting to HCF or ED*, and within 12 hours of injury.
4. The blood sample is collected within 3 hours of presenting to HCF or ED, and within 12 hours of injury.

Exclusion Criteria:

1. Participating in an interventional, therapeutic clinical study that may affect the results of this study (an observational study would be acceptable).
2. Time of injury cannot be determined.
3. Primary diagnosis of ischemic or hemorrhagic stroke.
4. Venipuncture not feasible (i.e., skin integrity compromised at the venipuncture sites, blood vessel calcification (i.e., IV drug users, advanced atherosclerosis) both upper limbs missing (congenital or amputee)).
5. A condition precluding entry into the CT scanner (e.g., morbid obesity or claustrophobia).
6. The subject has a neurodegenerative disease or other neurological disorder including dementia, Parkinson's disease, multiple sclerosis, seizure disorder, brain tumors, and history of neurosurgery, stroke or TIA within the last 30 days.
7. Administration of blood transfusion after head injury, and prior to study blood draws.
8. The subject is a female who is pregnant or lactating.
9. The Subject is otherwise determined by the Investigator to be an unsuitable candidate for participation. If this criterion applies, a reason must be provided.