Potential TBI Biomarkers and Therapeutics

Developing a Blood Test for Brain Injury

Head CT scans are currently the standard evaluation method for traumatic intracranial injuries. However, the potential for adverse radiation exposure, high cost and unnecessary use of resources, and limited utility for mTBIs have led to exploration of other solutions to diagnose and evaluate mTBI in Service members. Researchers at Banyan Biomarkers (San Diego, CA) performed a clinical trial to validate two brain-specific protein markers that rapidly appear in the blood after TBI, ubiquitin C-terminal hydrolase-L1 (UCH-L1) and glial fibrillary acid protein (GFAP), as potential biomarkers for intracranial injury. The study design involved recruitment of patients admitted to emergency departments with suspected TBIs that also received a CT scan and blood withdrawal within 12 hours of injury. The serum was analyzed for concentrations of UCH-L1 and GFAP. Patients with concentrations above a defined threshold were considered positive for traumatic intracranial injuries. The study found that while only six percent of patients with a TBI (determined by Glasgow Coma Scale scoring) had injuries detected by CT, 66 percent were found to be positive for the UCH-L1 and GFAP test. The test had a sensitivity of 0.976 and a negative predictive value of 0.996 for detection of intracranial injuries. These efforts have resulted in the development of the Banyan Biomarkers BTI™ brain trauma indicator assay. After an injury, the assay can identify UCH-L1 and GFAP concentrations in the blood. Medical professionals can use this objective information to evaluate patients with suspected mild TBI, potentially reducing the need for CT scans.

The U.S. Food and Drug Administration (FDA) approved Banyan Biomarkers to market their Brain Trauma Indicator (BTI™) brain trauma indicator assay. This is the first FDA-authorized blood test for TBI and concussions.

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