Traumatic brain injury: NIH-funded researchers will assess biomarkers for diagnosis and treatment

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Biomarkers in the bloodstream could provide physicians with a quick and accurate method of assessing the severity of traumatic brain injury (TBI) and helping deliver and monitor the results of therapies, such as progesterone treatment.

Researchers at Emory University School of Medicine, using a new $2.2 million, five-year grant from the National Institutes of Health, will study biomarkers in the blood of TBI patients, working with colleagues at the Medical University of South Carolina, the University of Pittsburgh, the University of Michigan and Banyan Biomarkers, Inc. The patients will already be enrolled in the NIH-funded Phase III clinical trial called ProTECT III (Progesterone for Traumatic brain injury, Experimental Clinical Treatment), assessing the use of progesterone to treat TBI in 1,140 patients at 17 centers nationwide.

"Rapid clinical assessment of the severity of traumatic brain injury (TBI) is a critical factor in diagnosis, treatment and prognosis. Yet current methods of assessment are inadequate and often inaccurate and there is a tremendous need for improvement," says Michael Frankel, MD, professor of neurology at Emory School of Medicine, Director of Grady Hospital's Marcus Stroke & Neuroscience Center, and principal investigator of the NIH-sponsored biomarker grant.

According to the Centers for Disease Control and Prevention,

approximately 1.4 million Americans sustain a traumatic brain injury (TBI) each year, leading to 275,000 hospitalizations, 80,000 disabilities, and 52,000 deaths. In the Iraq/Afghanistan conflicts, approximately 20 percent of combat personnel suffer TBI.

Acute TBI leads to a cascade of cellular events set in motion by the initial injury that ultimately lead to cerebral edema (swelling of the brain), cellular disruption and sometimes death. Tissue breakdown leads to the release of proteins into the bloodstream. Several studies have shown that blood biomarkers correlate with outcome after TBI. Although preliminary studies suggest that serum levels of four biomarkers may more accurately predict the extent of injury than the commonly used Glasgow Coma Scale and CT scan, these have not yet been established as a reliable clinical tool.

Using the large patient group in the ProTECT III trial, the researchers hope to validate promising TBI biomarkers as predictors of clinical outcome and also evaluate the relationship between progesterone treatment, biomarker levels and outcome.

In an earlier pilot clinical trial several years ago, Emory researchers concluded that giving progesterone to trauma victims shortly following brain injury is safe and may reduce the risk of death and long-term disability. This led to the multicenter Phase III ProTECT trial currently underway.

"This new biomarker study should allow us to refine risk assessment for patients with moderate and severe TBI and evaluate the relationships between progesterone levels, serum biomarkers of structural injury in the brain, and clinical outcome," says Frankel. "This will not only help us assess the effectiveness of using progesterone to treat TBI, but will lead us to a more tailored approach for treatment of these patients."

Frankel also has been working as the principal investigator of another NIH-funded study in the innovative field of biomarkers, gathering data from the blood of stroke patients to determine who is at highest risk for recurrent stroke.

Provided by Emory University

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