

US DEPARTMENT OF DEFENSE BLAST INJURY RESEARCH PROGRAM COORDINATING OFFICE

Therapy Development for TBI and Related Symptoms Progesterone for TBI, Experimental Clinical Treatment (ProTECT III) Trial

An effective medical treatment for TBI does not currently exist. Progesterone is inexpensive, safe, and early studies showed progesterone's potential to be an effective treatment for moderate and severe TBI. ProTECT III was a phase three, randomized, double-blind, placebocontrolled clinical trial that evaluated the utility and efficacy of intravenous progesterone in moderate and severe TBI when compared to placebo, using the six-month Glasgow Outcome Scale Extended as the primary outcome measure. The trial was funded by the National Institute of Neurological Disorders and Stroke (NINDS) and was conducted through the Neurological Emergencies Treatment Trials network. This network is made up of 17 civilian sites with affiliate hospitals. The only DoD site to participate in ProTECT III was the Wilford Hall Ambulatory Surgical Center, a USAF medical treatment facility (operated by the 59th Medical Wing) at San Antonio's Lackland Air Force Base. Results of the trial were published in the New England Journal of Medicine on 10 December, 2014 (Wright et al., 2014). ProTECT III did not show a benefit of progesterone over placebo in the improvement of outcomes in patients with acute TBI.