

Study to look at progesterone's effect on kids with traumatic brain injury

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A University of Michigan researcher has received a two-year, \$600,000 grant to plan a randomized controlled study of progesterone to treat traumatic brain injuries in children.

A multi-center study on the use of [progesterone](#) for [traumatic brain injury](#) in adults is currently underway in the Neurological Emergencies Treatment Trials Network but it excludes children.

Previous single-center human studies have shown promising results in adults. It is also important to research the hormone's effect on the pediatric population for both safety and efficacy, says Rachel Stanley, M.D., M.H.S.A., assistant professor of Emergency Medicine and Pediatrics in the Department of Emergency Medicine.

Traumatic brain injury (TBI) is the leading cause of death from trauma, and of death in children. Despite the frequency of TBI (more than 1 million annual cases), its impact on the health of children, and decades of research on the topic, no effective treatment exists for children with TBI.

“Many trials of possible therapies for TBI in children have failed,” Stanley says. “Conducting future multicenter clinical trials of therapies for TBI requires substantial planning and innovative thinking.”

Recent studies have shown that progesterone administration is safe in adults and may have a substantial neuro-protective effect when

administered to adults with TBI.

A large ongoing multi-center trial of progesterone for TBI excluded children because administration of “sex steroids” (like progesterone) to children during growth is untested. Given the differences in TBI between children and adults, there is a need to adequately plan for a study of the safety and efficacy of progesterone for children with TBI, Stanley says.

Stanley will lead the planning for the execution of a multi-centered, national, U-M-led study that will address issues related to pediatric patient safety in the emergency department, improving care for injured children in rural settings and innovative treatments for traumatic brain injury. Dr. Nathan Kuppermann, M.D., M.P.H., Professor of Emergency Medicine and Pediatrics and Bo Tomas Brofeldt Endowed Chair of the Department of Emergency Medicine at the University of California Davis will serve as the co-principal investigator on the study.

Progesterone is a potent neurosteroid that is naturally synthesized in the central nervous system. Animal studies have shown that early administration of progesterone after experimental traumatic brain injury reduces cerebral edema, neuronal loss, and limits behavioral deficits in laboratory animals. Progesterone is an ideal candidate for treatment of TBI for several reasons. Progesterone enters the brain rapidly and reaches equilibrium with the plasma within an hour of administration. Progesterone also has a long history of safe use in men and women.

For the children’s study, the project will be coordinated through the Pediatric Emergency Care Applied Research Network (PECARN), the only federally-funded pediatric emergency research network in the U.S. PECARN conducts high-priority, multi-institutional research on the prevention and management of acute illnesses and injuries in children and youth of all ages.

PECARN has completed several large, multicenter, clinical studies including a prospective observational study of nearly 45,000 children with head injuries at 25 hospitals. This puts PECARN in an ideal position to plan and conduct a future safety and efficacy trial of progesterone for TBI in children.

The planning project will establish the inclusion/exclusion criteria and outcomes for a future trial, conduct an observational study at 15 PECARN sites to determine how many sites are necessary for a future trial and timing of arrival of a legal guardian for consent purposes. The end product of this planning project will be a protocol for a large safety and efficacy trial of [progesterone](#) for pediatric traumatic brain injury. This project is currently under way with an end date of the fall of 2012.

Traumatic brain injury statistics:

- Brain injury is the most frequent cause of disability and death among children in the United States. More than one million children sustain brain injuries every year and approximately 165,000 require hospitalization.
- Children aged 0 to 4 years, older adolescents aged 15 to 19 years, and adults aged 65 years and older are most likely to sustain a TBI.
- Almost half a million (473,947) emergency department visits for TBI are made annually by [children](#) aged 0 to 14 years.

Provided by University of Michigan

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