

News Release: [Research](#), [School of Medicine](#)

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# Emory Announces Phase III Study of Progesterone for Traumatic Brain Injury

## NIH Grant Will Allow Nationwide Network to Study Effects of Hormone's Effectiveness

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Emory University officials this week announced the third phase of a groundbreaking study to evaluate the effectiveness of the hormone progesterone on acute traumatic-brain-injured patients.

Backed by a grant from the National Institutes of Health (NIH), the Emory-led, multicenter, randomized double-blinded study (ProTECT III) will enroll 1,140 patients at 17 medical centers in 15 states. Atlanta's Grady Memorial Hospital will serve as the lead center, led by Emory University School of Medicine faculty researchers, in concert with colleagues from the Morehouse School of Medicine.

The initial award will be for three years and a total of approximately \$14.5 million, in order to demonstrate target feasibility to conduct the trial. If milestones are met during the first three years, the trial could be extended for three more years with additional funding of approximately \$14 million.

David Wright, MD, assistant professor of emergency medicine at Emory School of Medicine is the national study's lead investigator. Michael Frankel, MD, Emory professor of neurology, will serve as principal investigator of the clinical trial at Grady. The University of Michigan will provide the central study oversight and coordination. Data analysis will occur at the Medical University of South Carolina.

Emory researchers concluded in an earlier clinical trial that giving progesterone to trauma victims shortly following brain injury appears to be safe and may reduce the risk of death and long-term disability. Their three-year study, called ProTECT (Progesterone for Traumatic brain injury--Experimental Clinical Treatment) enrolled 100 participants. It was designed to evaluate whether progesterone can be administered intravenously in a safe and reliable way.

"We found evidence that progesterone is not only safe for use in patients suffering from traumatic brain injuries - showing no evidence of side effects or serious harmful events. We also found a 50 percent reduction in mortality in those patients treated with progesterone," says Wright. "Furthermore, we found signs that progesterone improved functional outcomes and reduced disability in patients with moderate brain injury. But this was a small, pilot study. By expanding our test sites to 17 major trauma centers across 15 states and enrolling more than 1,000 patients, we hope to confirm these preliminary findings and determine if progesterone benefits victims of acute traumatic brain injury."

Although it is widely considered a "sex steroid," progesterone is also a protection hormone. It is naturally present in small but measurable amounts in the brains of males and females. Human brain tissue is loaded with progesterone receptors. Laboratory studies suggest that progesterone is critical to the normal development of neurons in the brain and exerts protective effects on damaged brain tissue.

Donald G. Stein, PhD, Asa G. Candler Professor of Emergency Medicine at Emory School of Medicine and director of Emory's Department of Emergency Medicine Brain Research Laboratory, pioneered discoveries regarding the effect of progesterone following traumatic brain injury - first discovering the neuro-protective properties of progesterone in the laboratory more than 25 years ago.

"The results that we are now seeing, and hope to continue validating, are an incredible and gratifying reward for more than 25 years of concentrated research," says Stein. "My work first started when I began to notice evidence that women tended to respond to treatment and recover better than men suffering from brain injury and stroke. Many people do not realize that it's not just a female hormone; both men and women produce progesterone directly in the brain, as well as other tissue. Ultimately I learned that progesterone basically does in brain injuries what it also does during fetal development - protect cells and tissue. To now witness the translation of this laboratory research into a treatment that may have life-saving benefits is breathtaking."

Every 15 seconds, a U.S. citizen sustains a significant traumatic brain injury, with approximately 1.5 million adults and children in the United States suffering from these injuries each year, leading to 50,000 deaths and 80,000 new cases of long-term disability, according to the Centers for Disease Control and Prevention. Despite the enormity of the problem, scientists have failed to identify effective medications to improve outcomes following a traumatic brain injury.

"The beginning of this nationwide clinical trial with support from the NIH is the result of many years of research by our dedicated faculty scientists and physicians, who have persevered in their belief that this treatment has the potential to save and improve lives," says Thomas J. Lawley, MD, dean of Emory School of Medicine. "I am extremely proud of their efforts and the partnership with Grady Hospital that has allowed the research to progress to this exciting point."

According to Michael Young, CEO of Grady Health System, benefits from the collaboration between the region's only Level I Trauma Center and Emory University researchers and physicians will reach far beyond the city and state.

"The NIH grant is more than an outstanding achievement for Emory, it is a significant advancement in the care that Grady Hospital will be able to provide our brain trauma patients," says Young. "The research and cutting-edge treatment resulting from this grant will once again demonstrate that the Emory-Grady partnership improves the quality of life for patients here and well beyond the metro Atlanta area."

Traumatic brain injuries have also been labeled the "signature wound" of U.S. soldiers in the field of battle - particularly in recent conflicts in Iraq and Afghanistan, and the number of military personnel impacted by blunt trauma traumatic brain injury has risen dramatically in recent years. While greater improvements in armored technology have spared many more lives, more soldiers are now facing the consequences of their brain injuries. The development of progesterone therapy could allow more of these soldiers to return home with significantly reduced therapy needs and costs.

"I am extremely pleased by the decision of the National Institutes of Health to award grant funding for research on possible treatments of acute traumatic brain injury (TBI) to Emory University," says U.S. Sen. Saxby Chambliss (R-Ga.) "TBI has become the signature injury of the wars in Iraq and Afghanistan, and too many of our warriors are returning home with life-altering injuries. We have to continue to find ways to treat this extremely complicated injury, and this grant is a step in the right direction. However, this injury is not unique to our military service members. The research Emory will conduct with support from Grady Hospital will also be invaluable to the population at large. More than one million people are affected by this injury every year. I am very proud of Emory for being selected for this grant and hope the research yields promising results."

"Effective drug therapies are desperately needed for traumatic brain injury. Progesterone has shown protective effects in animal models of head injury, and was tested for safety in a small clinical trial" ;

Walter Koroshetz, MD, deputy director of the National Institute of Neurological Disorders and Stroke (NINDS), the NIH institute that is providing primary support for the study.

"The brain injury community is hopeful that this large trial will establish whether emergent administration of progesterone is beneficial in patients," says Koroshetz. "Since it is an inexpensive, FDA approved drug, and easy to administer, it could be made available to patients quickly."

Emory University has licensed technology for the use of progesterone in traumatic brain injury to Besins Healthcare SA. Drs. Wright and Stein are inventors of novel technology related to this research and under Emory policies are eligible to receive a portion of any royalties or fees from this technology that are received by Emory. Dr. Stein is also a consultant to BHR Pharma, LLC, the R&D affiliate of Besins. These relationships have been reviewed and managed by Emory University in compliance with its conflict of interest policies.

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The Robert W. Woodruff Health Sciences Center of Emory University is an academic health science and service center focused on missions of teaching, research, health care and public service. Its components include the Emory University School of Medicine, Nell Hodgson Woodruff School of Nursing, and Rollins School of Public Health; Yerkes National Primate Research Center; Emory Winship Cancer Institute; and Emory Healthcare, the largest, most comprehensive health system in Georgia. Emory Healthcare includes: The Emory Clinic, Emory-Children's Center, Emory University Hospital, Emory University Hospital Midtown, Wesley Woods Center, Emory University Orthopaedic Spine Hospital, the jointly owned Emory-Adventist Hospital, and EHCA, a limited liability company created with Hospital Corporation of America. EHCA includes two joint venture hospitals, Emory Eastside Medical Center and Emory Johns Creek Hospital. The Woodruff Health Sciences Center has a \$2.3 billion budget, 18,000 employees, 2,500 full-time and 1,500 affiliated faculty, 4,300 students and trainees, and a \$5.5 billion economic impact on metro Atlanta.