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Grady testing breakthrough for traumatic brain injury

Atlanta Business Chronicle - by [Urvaksh Karkaria](#) Staff Writer
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An Emory University

researcher has developed what could be the first drug therapy to treat traumatic brain injury — a condition that affects more people than breast cancer, prostate cancer and HIV combined.

Grady Memorial Hospital is leading a national clinical trial to test the effectiveness of the



Joann Vitelli

Research on the brain: Drs. David Wright, left, and Donald Stein are instrumental in developing what could be the first drug therapy to treat traumatic brain injury.

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therapy, which aims to use the hormone progesterone to halt the negative chain of events triggered in the brain following a traumatic head injury.

If the trial is successful, this “could end up being the standard of care for traumatic brain injuries,” said Dr. Darryl Kaelin, medical director of the acquired brain injury program at **Shepherd Center**.

The National Institutes of Health-funded trial promises to elevate Grady's reputation as a top-notch research institute.

Clinical trials are an area of focus at Grady, with the hospital involved in more than 100 trials, hospital President and CEO Michael Young said.

“We have several millions of dollars of studies going on at any one time here,” he said. “We are making a concerted effort to grow there, and to make sure we capture more revenue in the research that's already under way.”

Laboratory studies suggest that progesterone, naturally present in small amounts in the brain, is critical for the development of neurons in the brain and protects damaged brain tissue.

The Phase III trial, which will enroll 1,140 patients in 15 states, could stretch up to six years and draw about \$28 million in NIH funding.

Early-stage trials revealed progesterone cut traumatic brain injury related deaths by about 50 percent. It also showed cognitive, sensory and motor improvement within one month of injury, and reduced disability in patients with moderate brain injury.

The therapy targets a large and lucrative market. About 1.5 million to 2 million people in



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the United States suffer from head 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**.

The therapy, under trial, has been licensed to BHR Pharma LLC, a Herndon, Va.-based pharmaceutical research and development company. BHR is conducting a separate trial to study the effectiveness of progesterone in treating traumatic brain injury.

Dr. Don Stein, director of Emory's **Department of Emergency Medicine, Brain Research Laboratory**, has spent the past 27 years and about \$4 million developing the therapy.

"[Stein is] probably the lead investigator in the use of progesterone for its treatment in central nervous system injury in the country, if not the world," Kaelin said.

How it works

When a patient suffers traumatic head trauma, chemicals flood into the brain and trigger a cascade of negative events, including inflammation. A chemical overload in the brain flips the "death switch" in cells, essentially making the cells commit suicide, said Dr. David Wright, the trial's principal investigator and an emergency room physician. The inflammation increases the pressure in the brain, causing brain damage and eventually death.

Researchers hope progesterone will prevent the chemicals from triggering the "death switch" and control the brain's swelling.

Progesterone is a potent developmental hormone, Stein said.

"It's no surprise that when a woman becomes pregnant, her progesterone levels go up tenfold and stay elevated till the baby is born," he said. "It does a lot of things to help protect the fetus."

Stein said he stumbled upon progesterone's positive effect on the brain.

"When I first started this work, I wasn't looking for [progesterone] as a treatment," he said. "Sometimes it's good luck."

Stein initially was studying the role of sex differences in the outcome of brain injury following reports that women tend to handle trauma and stroke better than men.

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