

UC Davis to study drug therapy to minimize death and disability from traumatic brain injury

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A clinical trial of a new neuroprotective drug for people with traumatic brain injuries will be offered to patients seen in UC Davis Medical Center's level-1 trauma center, through an \$8 million grant funded by the Congressionally Directed Medical Research Program of the U.S. Department of Defense.

The study's primary aim is to determine whether the drug, a neuroactive steroid called allopregnanolone, would be an effective treatment for severe brain injuries such as those occurring in car crashes, sports and recreation accidents and falls. Active duty military personnel in war zones also experience severe brain injury as a result of blasts from the explosion of makeshift bombs or improvised explosive devices.

The study will take place over five years and will be led by Michael Rogawski, professor and chair of the Department of Neurology in the UC Davis School of Medicine, who is highly regarded for developing new drug treatments for patients with epilepsy.

"Allopregnanolone has never been tested in humans with brain injuries but it has been shown to be effective in animal models," Rogawski said. "We believe that this approach can provide patients with improved survival and cognition and better overall neurological outcomes. We also will be looking to see if it prevents the development of post-traumatic epilepsy."

"Post-traumatic epilepsy is a major complication of traumatic brain injury that is associated with psychosocial disability and may be a contributing factor to premature death after head injury," Rogawski said. "The incidence of post-traumatic epilepsy is 10 to 15 percent for adults with severe brain injuries and has been as high as 50 percent in the military."

Allopregnanolone is a steroid that protects against seizures and brain injury. It is produced in the body from the female sex hormone [progesterone](#). Recently, progesterone has been studied and found promising for treating brain injury in humans. But it is difficult to formulate and administer and produces hormonal side effects, Rogawski said. In animals, allopregnanolone is more potent than progesterone in treating traumatic brain injury and it does not have progesterone's hormonal activity, he said.

Whether from car crashes or the explosion of bombs in war-torn countries, more than 1.4 million Americans suffer head injuries each year and 50,000 people die from them, according to the U.S. Centers for Disease Control and Prevention. More than 5 million people — about 2 percent of the population — are left with long-term or lifelong disabilities as a result of [traumatic brain injury](#).

All 18- to 59-year-old patients with severe blunt or penetrating head trauma seen in the UC Davis Medical Center emergency department will be approached to participate in the clinical trial. Patients who enroll will receive either allopregnanolone or a placebo within hours of a brain injury and at regular intervals over a five-day period.

Researchers hope to enroll 136 male and female patients to determine whether receiving the drug minimizes brain damage, reduces or eliminates post-traumatic epileptic seizures, and improves patients' psychological functioning and overall quality of life.

UC Davis will manufacture allopregnanolone through the UC Davis Institute for Regenerative Cures' Good Manufacturing Practices Facility directed by Gerhard Bauer, an assistant professor of hematology and oncology. Kate Marusina of the National Institutes of Health (NIH)-funded Clinical Translational Science Center is assisting with Food and Drug Administration regulatory filings.

"This is a unique study because UC Davis is sponsoring the trial and is also manufacturing the drug to be used in the clinical trial," Rogawski said.

Provided by University of California - Davis

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