

Centers in Ariz. will test brain injury drug

By Sonja Haller

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Valley doctors participating in a clinical trial are optimistic that a drug may finally allow them to treat traumatic brain injuries while saving lives and reducing long-term disabilities.

Four Arizona medical institutions are participating in the study of the hormone progesterone to treat blunt trauma from causes such as car accidents, falls and assaults.



Joseph Zabramski

investigator at Scottsdale Healthcare Center.

"This is the most promising drug we've seen, and there's no evidence of side effects," said Dr. Joseph Zabramski, a neurosurgeon and the study's principal investigator at Scottsdale Osborn Medical

Doctors do what they can to monitor pressure on the brain and maintain a patient's blood pressure and oxygen levels. But without a drug proven to improve brain-functioning outcome, they have been telling family of brain-injury patients for years "we'll wait and see," Zabramski said.

In addition to Scottsdale Healthcare, Banner Good Samaritan Medical Center in Phoenix, the University of Arizona's Arizona Emergency Medicine Research Center, and the Maricopa Integrated Health System also are participating in the clinical trial, called PROTECT III.

The hospitals are anywhere from 30 to 60 days from being ready to have their first patient participate.

The \$14.5 million study is being funded by the National Institutes of Health and conducted at 17 medical centers across the nation.

Progesterone is often thought of as a female hormone that helps support pregnancy but also is present in males.

In treating a brain trauma, the hormone must be administered within four hours of the injury

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and given over four days. It is believed to prevent swelling of tissues and cell death.

U.S. Rep. Gabrielle Giffords would not have been a candidate for the study because it does not include penetrating injuries such as a bullet wound.

Every 15 seconds, someone in the United States receives a significant traumatic brain injury, according to the Brain Injury Association of America.

"I think when you look at brain injury as the Number 1 cause of prolonged disability among young people, you have to recognize that this has a huge potential impact on trauma and society in general," said Dr. Ara Feinstein, principal investigator of the study at Banner Good Samaritan Medical Center. "Nothing has come along like this in trauma care in the last 30 years."

This trial is the final step before progesterone may routinely be used to treat brain injuries.

This study follows a much smaller trial of 100 patients who were given progesterone soon after a traumatic brain injury. The study's authors reported in 2007 that those patients were 50 percent less likely to have died than those given a placebo.

Dr. Patrick J. O'Neill, director of the Surgical Intensive Care

Unit and of the Surgical Critical Care Residency at Maricopa Medical Center, said that brain cells that are dead, are dead. But those that are injured need support as soon as possible.

"The hope is that progesterone can modulate that secondary inflammatory process," he said. "The thought is that it will decrease the post-injury inflammatory process so that those neurons can heal properly."

The scope of the study is to enroll 1,200 patients over four years, but it's not expected to take that long. Patients must be at least 18 to participate. Patients either will receive progesterone or a placebo intravenously, and researchers will assess patients' conditions over six months.

Because the progesterone must be given to patients within hours of being injured, neither patients nor their families may be able to consent to participating in the trial in some cases. Patients may be provided the progesterone without their consent when they are taken to one of the four medical centers. People can opt out of the study by calling the UA's Arizona Emergency Medicine Research Center at 602-827-2140. If people opt out, they will be provided a gray wristband that identifies them as non-participants in the event they are taken to one of the sites after an injury.