Public Announcement for an Emergency Research Study of Traumatic Brain Injury in Southeast Wisconsin

Researchers at the Medical College of Wisconsin are studying the best way to treat brain injuries.

This notice is to inform you of a research study of a traumatic brain injury that will begin in southeast Wisconsin in May 2015 by the Medical College of Wisconsin. This national study will compare a new medicine, Tranexamic Acid (TXA), for a traumatic brain injury to regular medical care with no TXA. This new treatment could save lives and reduce brain damage after serious brain injuries.

What happens when someone has a traumatic brain injury?

Traumatic brain injuries, such as brain injuries suffered in a car accident or fall, are the leading cause of death for young adults. Every year, more than 1.6 million people sustain a traumatic brain injury resulting in 80,000 people with permanent brain damage and 52,000 deaths. When patients experience a serious traumatic brain injury, there is often bleeding in and around the brain as well as brain swelling. The bleeding and the swelling are caused by injuries to the brain and may cause people to die or have severe brain damage after an injury.

Why do we need to do this research?

Right now, there is no known medicine that will stop the bleeding and keep the brain from swelling. Researchers have found that an approved medicine for bleeding called Tranexamic acid (TXA) may decrease bleeding in the head and swelling of the brain. TXA is a medicine commonly given to control bleeding. This research is comparing TXA to regular medical care with no TXA to find out whether TXA can reduce brain damage and death in patients with traumatic brain injury. Adults are randomly chosen (like flipping a coin) to get TXA (2 different doses) or no medicine. The TXA or a fluid without TXA (for the people receiving no medicine) will run for 8 hours. All patients will receive all other standard treatments for traumatic brain injury.

Are there risks to this research?

All research has risks. Rarely, overdoses of TXA may cause eyesight problems, nausea, vomiting, and seizure. If given too quickly, TXA may cause low blood pressure. In patients with head injury, low blood pressure may make a brain injury worse and possibly increase risk of death. TXA is given carefully in this study to prevent low blood pressure. Other risks are: blood clots, skin irritation, or rash due to a minor allergic reaction, and severe allergic reaction (anaphylaxis, a severe allergic reaction which can result in decreased blood pressure, airway swelling, or death). These potential risks are not expected to be worse in the people that receive TXA

this study will kept private. The findings from this study will be shared at meetings and in scientific journals to help others, but information that could identify a