

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 because it has been used safely in many hospitals to treat bleeding problems. However, researchers will watch for this and stop the study if there are safety concerns. There may also be some unknown risks because the medicine used in this study is new for treating brain injury. Every precaution will be taken to assure personal safety. All information obtained from

this study will be 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 person will not be used.

What is the benefit of this research?

This study may help others in the future. Because TXA treatment may lead to less bleeding and swelling, there is a potential benefit. TXA could reduce brain damage caused by brain injury and lead to improved brain function. This benefit is not guaranteed. People will not receive money for being in this research study and it will not cost a person anything.

If you are a young adult over 18 years of age and live in Southeast Wisconsin, you may be in this study.

Adults in Southeast Wisconsin that have a moderate to severe traumatic brain injury, are at least 18 years old, and are served by Milwaukee County Emergency Medical Services (EMS) or Flight for Life can be in this study. The paramedics will need to be able to start the study medicine within 2 hours of an injury to have potential to work. Treatment of a traumatic brain injury is an emergency and the paramedics have to act quickly to treat a person. This means that there is no time to get permission. People with traumatic brain injury are unconscious and cannot agree to join. In studies like this, a person's consent is not possible. This is called an exception from informed consent for emergency circumstances. That means, if you do not want to be in this study, you must request that you not be included. You will be given a bracelet or necklace to wear that tells emergency services that you are not part of the study. You will still receive regular treatment if needed. The U.S. Food and Drug Administration requires that researchers notify communities in cases when consent is not possible due to an emergency (FDA Code of Federal Regulations, Title 21, Section 50.24). We are notifying you before the study begins in May 2015. This study will continue for approximately 1 year.

Opting out of this study

Anyone who does not wish to be enrolled in this study may opt-out by wearing an opt-out bracelet or necklace. The paramedics are trained to not enroll anyone who is wearing this bracelet or necklace. An opt-out bracelet or necklace may be requested free of charge by either calling the Resuscitation Research Center at (414) 805-6493 or email at RRC@mcw.edu.

Please contact us if you have any questions or concerns

If you have questions or concerns about this study or you do not want to participate, please contact Dr. M. Riccardo Colella, either by phone (414-805-6493), mail (Department of Emergency Medicine, 9200 W. Wisconsin Ave., Froedtert Hospital East, PV1, Milwaukee, Wisconsin 53226 or email (RRC@mcw.edu), or visit the web site at (www.mcw.edu/ROCTXA). Feedback from the community may be used to change the study.