



Progesterone for the treatment of Traumatic Brain Injury

Learn about a traumatic brain injury study that may affect you or someone you know.

Traumatic Brain Injury (TBI) is sudden damage to the brain caused by an outside force to the head – such as a car crash, a fall, or from something hitting the head. Did you know that every 15 seconds someone in the US suffers a major TBI, and every 5 minutes someone is forever disabled as a result of TBI? Are you aware that TBI is the leading cause of death and disability in children and adults 1-44 years of age?

TBI can affect a person's ability to think and remember things. It can also cause problems with balance and coordination. TBI can prevent a person from returning to work or functioning independently. TBI can cause permanent brain damage or even death.

ProTECT III is a research study designed to see if progesterone, a hormone normally found in our bodies, can reduce the amount of brain damage caused from a traumatic brain injury. Previous studies suggest that progesterone, given immediately after a TBI, may help treat brain injuries by reducing brain swelling and damage.

There is no specific drug treatment for traumatic brain injury. The reason for doing this study is to find out if progesterone is safe and if it works better than standard medical care alone in reducing the brain damage caused from a TBI.

Normally, researchers get permission (consent) before a person can be included in a research study. A person with a traumatic brain injury will not be able to give consent at the time of injury. Since TBI must be treated quickly, there might not be enough time to locate and talk to the person's next of kin about the study, so it's possible that a person might be enrolled in the study without the consent of his or her next of kin. This is called "Exception from Informed Consent" (**EFIC**). Once the legal guardian is located, they will be asked to give permission for you to continue in the study.

The purpose of this handout is to notify our community about this research study and to provide contact information and resources where you can learn more, including an option to decline participation.

Local ProTECT III Contact Information

University of Kentucky College of Medicine, Department of Emergency Medicine

Phone: 859-257-6703 / E-mail: rs_emmeddept@email.uky.edu

Websites: sitemaker.umich.edu/uky

www.protectiii.com



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