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## The TAMPITI Trial

This study is different than other research studies because it involves enrolling patients who cannot give consent and the treatment must be given immediately after injury. In order to do this research study without initial consent, we must meet with and inform the public through community outreach before this research study will be approved or started. Patients will be enrolled into this study without their consent unless they are wearing an OPT OUT bracelet that can be easily seen.

### The Problem

Bleeding is the most avoidable cause of death in trauma patients. Up to one-third (1/3) of severely injured trauma patients experience coagulopathy (a condition in which the blood's ability to clot is impaired) and as a result, many die from rapid and sudden blood loss. Current treatments (blood product transfusion, etc.) are often ineffective and new options are being sought. Tranexamic Acid (TXA), a drug that is already FDA approved for certain bleeding conditions, such as hemophilia and heavy menstrual bleeding, but not yet FDA approved for severe bleeding in trauma, is a NEW option we are planning to study here at Barnes Jewish Hospital/Washington University in St. Louis.

### Purpose

The purpose of this study is to evaluate the effects of TXA on the immune system, pharmacokinetics (the way the body absorbs and breaks down the medication), as well as TXA's safety and effectiveness in severely injured trauma patients

### Current Standard of Care

The current standard of care for trauma patients is to give sterile saline (salt water) through the veins on the way to the Emergency Room. When the patients arrive at the hospital, they are evaluated and are given blood products if they are bleeding.

### Study Duration

The TAMPITI TRIAL (Tranexamic Acid Mechanisms and Pharmacokinetics in Traumatic Injury) will take place at Barnes Jewish Hospital in the fall of 2015 through Spring of 2017 (specific dates to be determined).

### The Study Design

Patients 18 years and older admitted to the Barnes Jewish Hospital Emergency Room with a traumatic injury (e.g. car crash, gunshot wound, etc.) and are ordered by doctors to receive at least 1 blood product and/or require immediate transfer to the operating room AND are able to receive the study drug within 2 hours from time of injury will be included in the study. Once enrolled, they will be chosen at random to receive a placebo (inactive substance, salt water) in their IV, or dose 1 of an experimental drug, (TXA, 2 gram dose in their IV), or dose 2 of an experimental drug (TXA, 4 gram dose in their IV). After the IV treatment is given (placebo or TXA dose1 or TXA dose 2), each group will have blood samples collected at various time points. Blood samples and clinical information will be collected throughout the hospital stay up to 30 days after injury.

### What TXA Does:

TXA speeds up the process of blood clotting which, in the end, may improve survival.

For more information regarding this trial, please go to [www.TAMPITI.wustl.edu](http://www.TAMPITI.wustl.edu), email our study team at [tampititrial@wudosis.wustl.edu](mailto:tampititrial@wudosis.wustl.edu) or call our study team at 314-747-4185.