



# PREHOSPITAL TRANEXAMIC ACID USE FOR TRAUMATIC BRAIN INJURY

Medical College of Wisconsin Community Consultation

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Sponsored by: Resuscitation Outcomes Consortium,  
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# WHAT IS TRAUMATIC BRAIN INJURY (TBI)?

- Refers to an **INJURY** to the **BRAIN** produced by sudden physical **INJURY**, as from violence or accidents.
- The injury causes bleeding or swelling in the brain
- TBI is the leading cause of death in people younger than 40 years old
- People who have suffered from TBI may require specialized care including **MEDICATIONS** and **SURGERY**



# BACKGROUND



- 1.7 Million people suffer from TBI
- Each year in the US
  - 53,000 people die yearly
  - 5 million people live with TBI related disabilities
  - 80,000 people live with permanent SEVERE disabilities
  - 300,000 soldiers suffer from TBI or post-traumatic stress disorder (PTSD)
- TBI patients
  - have very high rates of post-traumatic stress disorder
  - are 50% more likely to suffer from depression
  - are 5-times more likely to develop Alzheimer's disease
  - are significantly more likely to suffer other long-term neurodegenerative consequences

# BACKGROUND

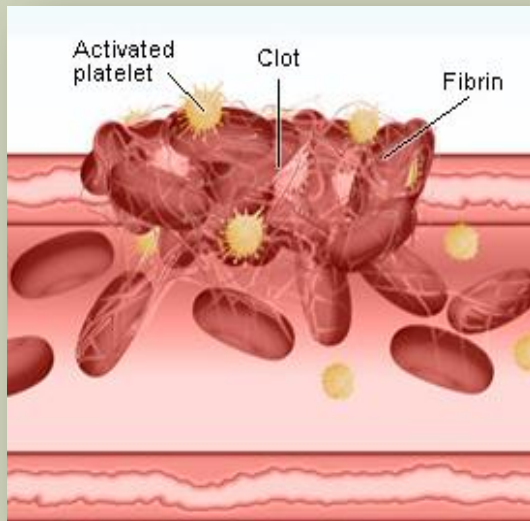
- Treatment of severe injury must be started quickly to limit the extent of bleeding/swelling
- Very few treatments exist
- Most of the existing treatments have not been tested or are not given soon enough after the trauma to limit injury
- Recent studies have shown that patients who received Tranexamic Acid (TXA) soon after injury did better than those who got TXA later or not at all
- Question remains: Do people who get TXA early have a better outcome than people who get standard care?



# WHAT IS THE TXA USE FOR TBI STUDY?

- This study involves research
- Multi-center study including at least 10 North American Level 1 trauma center sites
- Purpose: Determine if TXA started in the prehospital setting, as soon as possible after injury to people with suspected TBI have a better outcome than people who don't get TXA
- Plan: Enroll patients who are suspected to have a traumatic brain injury into a study giving them a medicine that may decrease bleeding and swelling in the head
- The knowledge gained will likely impact how well people recover their neurologic abilities after TBI

# WHAT IS TRANEXAMIC ACID?



- Tranexamic Acid or TXA is an antifibrinolytic medication used to control bleeding in many clinical settings
- Bleeding and swelling in the head occur after trauma
- To stop bleeding the human body makes clots
- When severe trauma occurs the body overreacts and it begins to breakdown the clots which may increase swelling
- TXA helps prevent breakdown of clots and may help decrease swelling

# PATIENT SELECTION

## Inclusion criteria

- Blunt or penetrating traumatic injury consistent with TBI
- Prehospital GCS (level of consciousness)  $\leq 12$  prior to administration of sedative and/or paralytic agents
- Prehospital SBP (systolic blood pressure)  $\geq 90$  mmHg
- Prehospital IV (intravenous access)
- Age  $\geq 18$  yrs (or weight  $\geq 50$  kg if age is unknown),
- EMS transport destination based on standard local practices determined to be a participating trauma center

## Exclusion criteria

- Prehospital GCS=3 with no reactive pupil
- Estimated time from injury to start of study drug bolus dose  $>2$  hours
- Unknown time of injury
- Clinical suspicion by EMS of seizure activity or known history, to the extent possible, of seizures, thromboembolic disorders, acute MI, or stroke
- CPR by EMS prior to randomization
- Burns  $> 20\%$
- Suspected or known prisoners
- Suspected or known pregnancy
- Prehospital TXA given prior to randomization
- Patients who have activated the “opt-out” process when required by the local regulatory board

# HOW ARE PATIENTS SELECTED FOR THIS STUDY?

- The Emergency medicine provider (EMS) responding to calls in the prehospital setting will use information obtained when they first come in contact with a patient at the scene of the injury
- The information includes blood pressure, pulse, type of injury, and level of consciousness
- The EMS will then look at whether the patient is eligible for the study
- For patients who are eligible for this study, the EMS providers will give the first dose of TXA, take the patient to the hospital, and notify the hospital pharmacist so they may prepare the maintenance dose of TXA



# WHAT ABOUT OTHER TREATMENTS AND CARE?

- People enrolled in this study will continue to receive all other treatments and care they would have received anyway
- If you are not in the study, the only difference would be that you would not get TXA

# HOW WILL THE TXA BE GIVEN?

## Bolus with Maintenance

- EMS gives 1 gram TXA bolus
- Hospital gives 1 gram TXA over 8 hours

## Bolus only

- EMS gives 2 gram TXA bolus
- Hospital gives placebo\* over 8 hours

## Placebo\* only

- EMS gives placebo\* bolus
- Hospital gives placebo\* over 8 hours

\* placebo=plain salt water

# IS TXA SAFE?

- Was first used in 1966
- TXA is approved by the U.S. Food and Drug Administration (FDA)
- Approved for use in certain types of bleeding patients- Ruptured intracranial aneurysms, upper GI hemorrhage, hemophilia, pediatric urinary tract surgery, cardiopulmonary bypass, liver transplantation, trauma
- All EMS providers and hospitals have established policies and procedures to safely give IV medicines

# WHAT WILL BE STUDIED?

- We will collect blood samples upon arrival and up to 48 hrs
  - Time points: at 0, 6, 12, 24, and 48 hours (or discharge from hospital - whichever occurs first)
  - Up to a total of **23 cc** of blood will be collected at each time point for research purposes
- The blood samples will be collected on all patients and stored for future tests (which WILL NOT include genetic testing) with the patient's approval
- Daily medical record and x rays/radiology tests will be reviewed
- The patient will be contacted by the study team before discharge or the 28<sup>th</sup> day and again at 6 months for a short survey to find out how they are doing

# ANY RISKS?

- As is possible with any new treatment, there are risks involved
- Patient safety is carefully monitored and recorded by an independent group for any complications of study treatments
- The patients in this study will be selected to receive
  - 1 gm TXA bolus with 1 gm TXA maintenance infusion or
  - 2 gm TXA bolus with placebo maintenance infusion or
  - placebo bolus and placebo maintenance infusion
- Risks include: nausea, low blood pressure, allergic reaction, at higher doses TXA has been associated with seizures and an increased risk of blood clots in the body

# WHAT IS THE INFORMED CONSENT PROCESS?

- The consent process is when we ask a person's permission and invite them to be in a study, explaining the risks and benefits, as well as answering any questions
- Patients will be unable to consent due to injury and the need for emergency treatment
- If possible, a script will be read providing the option to object to study enrollment
- Every attempt will be made to obtain consent from the legal representative to join or continue with the study or to refuse to allow the patient to join or continue in the study
- Enrolled patients will be informed of study when able and will be allowed to withdraw from the study

# INFORMATION YOU SHOULD KNOW

- Patients and/or their family members/legal representatives can decide at any time to withdraw from the study
- Patients will receive the same care whether they are not they are in the study
- There is no extra cost for being in the study; the patient will not receive compensation for being in the study
- If an injury occurs which is related to the study, the patient will not receive compensation for the injury and medical care will be available just as it is to the general community

# INFORMATION YOU SHOULD KNOW

- Every effort will be made to ensure patient privacy
- All data reviewed for the purposes of this study will be de-identified - personal identification such as name, medical record number will be removed
- The FDA may inspect the records at any time
- Members of the community may “opt-out” if they do not wish to be in the study. Opt-out bracelets are available for those who DO NOT want to be considered for this study. If the patient has the opt-out bracelet on, they will not be screened or enrolled in this study



# QUESTIONS?

- For questions pertaining to this study or if you would like to “opt out” of the study:

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- For questions pertaining to informed consent:

**MCW Human Research Protection Program**

**414-456-8844**

**THANK YOU**