



# PREHOSPITAL TRANEXAMIC ACID USE FOR TRAUMATIC BRAIN INJURY

Medical College of Wisconsin Community Consultation

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Sponsored by: Resuscitation Outcomes Consortium, US Department of Defense

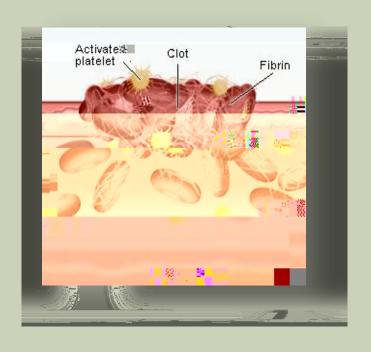
Refers to an INJURY to the BRAIN produced by sudden physical INJURY, as from violence or accidents.

The injury causes bleeding or

This study involves research

Multi-

## 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) 12 prior to administration of sedative and/or paralytic agents

Prehospital SBP (systolic blood pressure) 90 mmHg

Prehospital IV (intravenous access) Age 18yrs (or weight 50kg 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

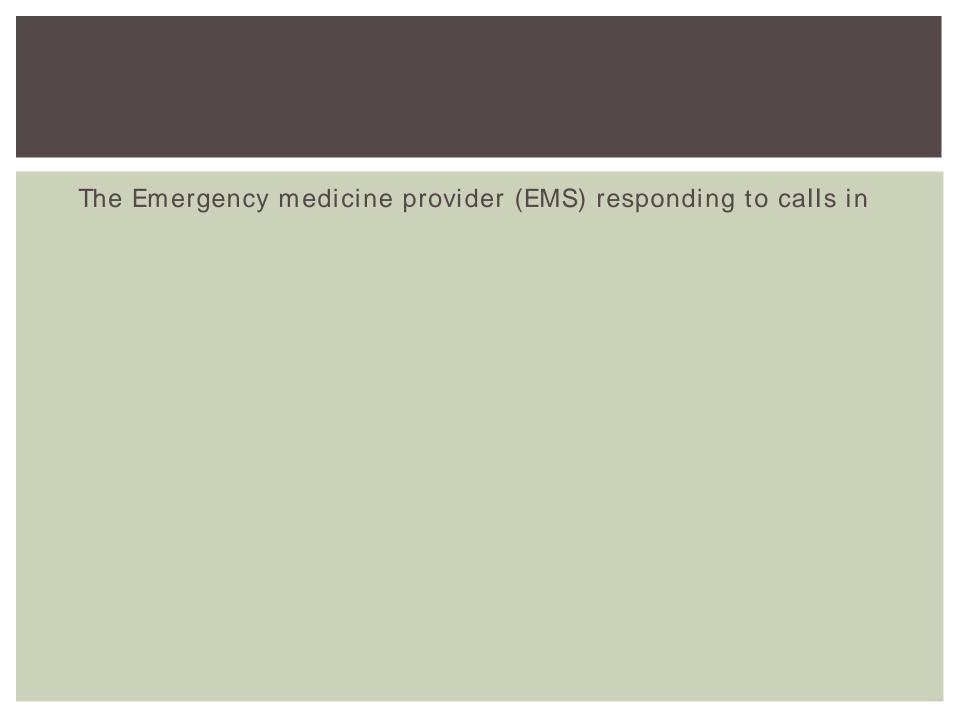
Unknown time of injury

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



# 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

<sup>\*</sup> placebo=plain salt water



## 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 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 T59()]T72(a)-72(i)-78(n)-77(3Tf28c-836)ey co sts





## 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



# **QUESTIONS?**

For questions pertaining to this study or if you would like

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For questions pertaining to informed consent:

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THANK YOU