



In partnership with **The University of Texas Health Science Center at San Antonio**

**For Immediate Release**

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## **Vasopressin Trauma Trial to Begin Enrollment** *Study aims to reduce death due to shock*

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**What are your odds of surviving a serious**

**car crash or other traumatic injury? Not good if your body loses a great deal of blood and goes into shock.** In fact, up to 50 percent of all trauma patients who go into shock die. A study that aims to reduce death due to hemorrhagic shock will begin enrollment at University Hospital within the next week. University of Texas Health Science Center at San Antonio (UTHSC) trauma surgeons will be testing Vasopressin, an FDA-approved medication that is routinely used to treat critically ill patients.

Over the next two to three years, approximately 350 trauma patients in shock will be enrolled in the FDA-approved Low Dose Vasopressin Trauma Trial that was approved for funding by the U.S. Navy last year. The purpose of the study is to determine whether rapid treatment with Vasopressin can reduce complications and death rates in patients who have suffered massive blood loss resulting in shock. Currently, patients in shock immediately receive intravenous saline fluid. Study participants will be randomized to receive either Vasopressin solution or saline fluid, in addition to routine care, upon arrival at the emergency center. Both study groups will receive all needed blood products. “This is not an experimental medication,” said Stephen Cohn, MD, UTHSC Chair of the Department of Surgery and principal investigator for the study. “Vasopressin is recognized by the American Heart Association for use in the management of patients in shock or as an alternative for patients in shock.”

Due to the fact these severely injured patients will be unable to give informed consent prior to enrollment, the study uses a provision for an exception from informed consent requirements in accordance with federal regulations (21 CFR 50.24). Patients, and their legally authorized representatives or family members will be notified at the earliest opportunity.

**-more-**

## UNIVERSITY HOSPITAL - TRAUMA TRIAL STARTS

### PAGE 2

A patient may withdraw or be withdrawn from the study at any time. If a patient is withdrawn from the study they will continue to receive treatment for their injuries and the quality of care will not be impacted.

This federal regulation allows the UTHSC Institutional Review Board (IRB) to approve a clinical trial without requiring informed patient consent provided specific criteria are met. These criteria include:

- Patients must be in a life-threatening situation
- The experimental treatment must offer patients the potential for direct clinical benefit in the form of increased survival
- The risks are reasonable
- Without an exception from informed consent the research could not be conducted

A prerequisite for study approval under these circumstances is public disclosure and community consultation. Fourteen community meetings were held in San Antonio and throughout the 22-county South Texas region comprising Texas Trauma Service Area P, so individuals could learn more and offer feedback.

This type of clinical research is vitally important since trauma-related injuries are the leading cause of death among Americans under the age of 45. According to the U.S. Centers for Disease Control and Prevention, more than 2 million people are seriously injured due to trauma in the U.S. each year.

Additional information on the Lose Dose Vasopressin Trauma Trial is available online at <http://www.surgery.uthscsa.edu/trauma/vcc/index.asp> or by contacting the project coordinator at the UTHSC Department of Surgery-Trauma at 210-567-3623. The project coordinator is also available to provide further information in person to community groups. Those who wish to be exempted from the study may also call this number to request a wristband to identify themselves as not wishing to be considered for participation (in the event they are critically injured).