



The University of Texas  
Health Science Center at San Antonio  
Mail Code 7840  
7703 Floyd Curl Drive  
San Antonio, Texas 78229-3900

Medical School  
Department of Surgery

(210) 567-5705 Chairman's Office  
(210) 567-3447 Chairman's FAX

September 19, 2006

Docket Number 95S-0158 (IND # 74154)  
Dockets Management Branch  
Food and Drug Administration  
Room 1061  
5630 Fishers Lane  
Rockville, Md. 20705-1266

RE: IND Number Assigned: 74,154  
Name of Sponsor: Stephen M. Cohn, M.D.  
Name of Drug: Vasopressin Intravenous  
Protocol: Prospective, Randomized, Double-Blind, Multi-Center Trial of Low Dose  
Vasopressin versus Placebo in Traumatic Shock Resuscitation

To Whom It May Concern:

Reference is made to our Investigational New Drug Application (IND) for Low Dose Vasopressin in traumatic shock resuscitation, IND #74154, which was submitted to the Center for Drug Evaluation and Research, Division of Cardiovascular and Renal Products on January 6, 2006, date of receipt January 10, 2006.

In conformance with 21 CFR 312.54(a) and the draft guidance for Industry entitled *Exception from Informed Consent Requirements for Emergency Research* (March 30, 2000) which require that Institutional Review Board (IRB) information concerning public disclosure be submitted to this Docket for clinical investigations involving an exception from informed consent [21 CFR 50.24(a)(7)(iii)], we provide documentation for the following site:

**University of Texas Health Science Center at San Antonio**  
7703 Floyd Curl Drive  
San Antonio, TX  
78229-3900  
**IRB:** University of Texas Health Science Center at San Antonio

If you have any comments or questions, please contact the undersigned at 210-567-5705.

Sincerely,

A handwritten signature in black ink, appearing to be "S. Cohn", written over a horizontal line.

Stephen M. Cohn, M.D., FAC.S.  
Professor and Chairman  
The Dr. Witten B. Russ Professor  
Department of Surgery

SMC:mbw

95S-0158

RPT 20

**PUBLIC RELATIONS REPORT FOR COMMUNITY CONSULTATIONS  
VASOPRESSIN STUDY**

SEE ATTACHMENTS FOR:

1. Outline of all media coverage by date
2. Community meeting fliers and advertisements
3. UTHSCSA and UHS internal articles
4. Copies of newspaper articles

**Vasopressin Trial - San Antonio  
Public Relations Report for Community Consultation**

March 30, 2006

Press Conference University Hospital  
Speaker: Stephen M. Cohn, M.D. and Ronald Steward, MD

Coverage Generated:

Express-News: March 31 Front Page, Metro Section:  
Patients may get test drug, not know

Associated Press Coverage:

WOAI. Com  
San Angelo Standard-  
KBTX-Bryan Texas

San Antonio Business Journal: Bizjournals.com  
Mysanantonio.com

Electronic Media:

KSAT-TV: 6 p.m.  
KENS-TV: 5 p.m.  
KABB-TV: 9 p.m.  
WOAI-TV: 6 p.m.  
KWEX-TV: 10 p.m.  
KVDA-TV: 10 p.m.

March 31

WOAI Radio 1200 AM – am drive  
KTSA 550 AM – am drive

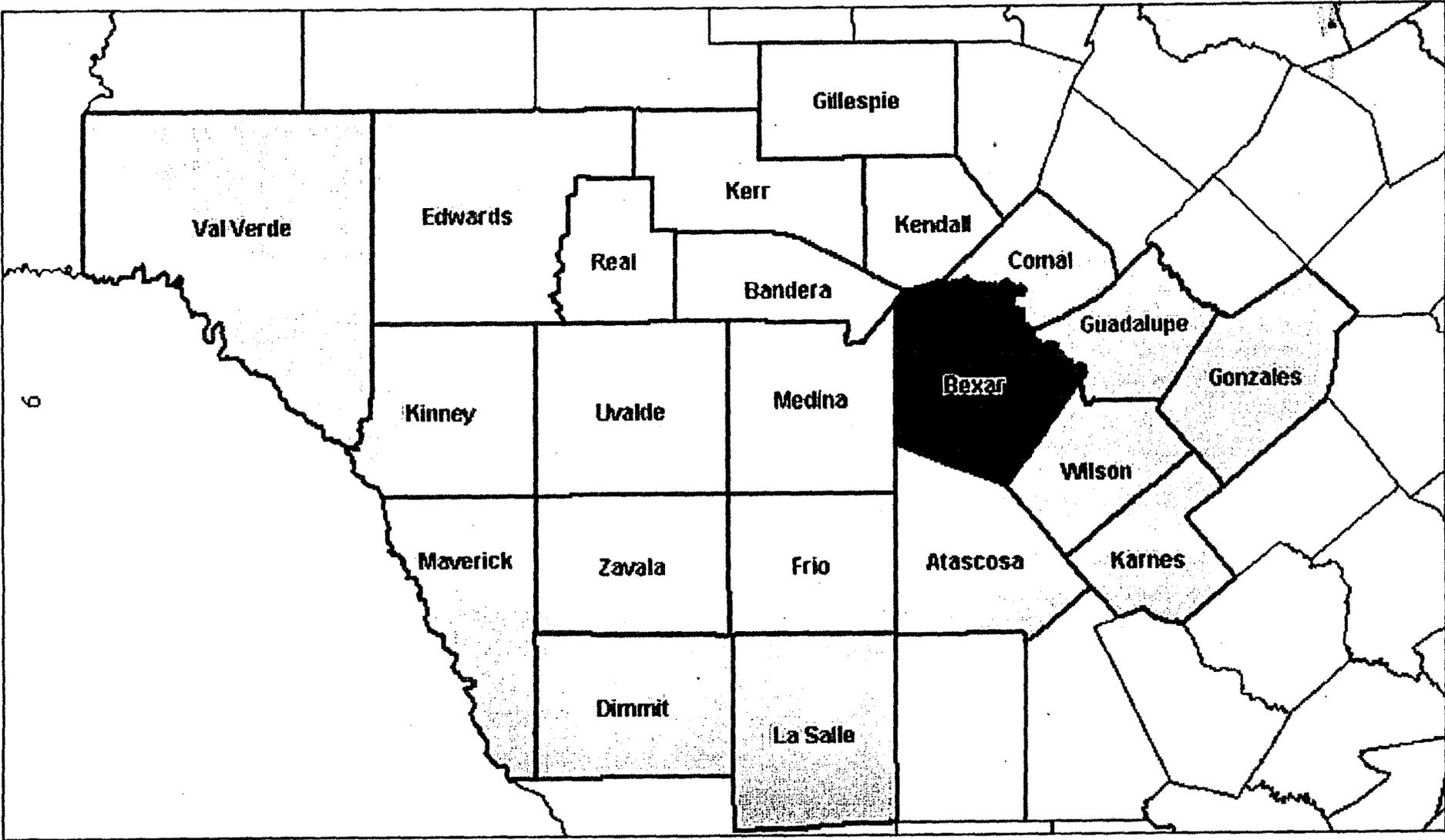
April 1, 2006 Victoria Advocate news article  
April 3, 2006 Kerrville Daily Times ¼-page advertisement  
April 4, 2006 Community Meeting Kerrville Library  
April 4, 2006 San Antonio Express-News: advertisement: 4 col. x 4/12 inches  
April 5, 2006 La Prensa: Bilingual newspaper: ½-page advertisement  
San Antonio Express-News: advertisement: 4 col. x 4/12 inches  
April 6, 2006 First San Antonio Community Meeting at  
The University of Texas at San Antonio  
April 10, 2006 Community Meeting: University Family Health Center – Southeast, SA  
April 11, 2006 Community Meeting: Pearsall Library  
Wilson County Paper ¼-page advertisement  
April 12, 2006 Community Meeting: Palo Alto College, SA  
Media- KVDA-TV(Spanish)  
WOAI- TV  
WOAI- pm drive  
Community Meeting: Floresville (Connally Memorial Hospital)  
April 17, 2006 Community Meeting: University Center for Community Health, SA

**Vasopressin Trial - San Antonio  
Public Relations Report for Community Consultation**

April 18, 2006	Community Meeting: University Family Health Center – North, SA New Braunfels Herald-Zeitung: ¼-page advertisement New Braunfels Herald-Zeitung article
April 19, 2006	Community Meeting: New Braunfels Library
April 20, 2006	Community Meeting: Eagle Pass Library
April 21, 2006	Community Meeting: Boerne Kendall County EMS
April 26, 2006	HISD – School Health Advisory council
April 27, 2006	Roseville Apartments

After repeated requests for UHS public relations department, there was no interest for public affairs program by COX Radio or Clear Channel Radio Stations.

# Trauma Service Area P



# You are invited to attend a **COMMUNITY MEETING**

**WHEN:**

**WHERE:**

Trauma-related injuries are a leading cause of death among Americans under 45 years of age. According to the Centers for Disease Control (CDC), each year more than 2 million people are seriously injured due to trauma.

University Hospital is seeking community approval to participate in a clinical study of a medication known as Vasopressin. Our study will test the use of low dose Vasopressin in trauma patients who are in shock. Trauma surgeons from The University of Texas Health Science Center at San Antonio (UTHSCSA) will be investigating Vasopressin's ability to increase survival in critically injured and bleeding patients.

Treatment would begin before arrival at the hospital, or immediately upon arrival at the hospital.

UTHSCSA trauma surgeons will be available to explain and answer questions about the study as well as the need to get an **exception from informed consent** requirements (i.e, receiving study treatment before giving consent), in accordance with federal regulations.

For more information please call 210-567-3623.



**You are invited to attend a  
COMMUNITY MEETING**

**WHEN: Wednesday, April 12  
6:30 – 8:00 p.m.**

**WHERE: Connally Memorial Hospital  
Floresville**

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*For more information please call 210-567-3623.*



# UNIVERSITY HEALTH SYSTEM

A Half Century of Health, Healing and Hope

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

**For Immediate Release**

Contact: University Health System  
Leni Kirkman or Julie Wiley  
(210) 358-2335  
UT Health Science Center  
Will Sansom  
(210) 567-2570

## **New trauma trial aims to improve survival of patients in shock** *Researchers seeking community input on exception to informed consent*

(SAN ANTONIO – MARCH 30, 2006) What are your odds of surviving a serious traumatic injury? Not good if your body goes into shock. In fact, a third to a half of all trauma patients who go into shock die, and trauma is the leading cause of death in all Americans under the age of 45. Finding a better way to treat patients in shock is the goal of a study to be conducted by University of Texas Health Science Center at San Antonio (UTHSC) surgeons at the Level I trauma center at University Hospital.

Ten meetings, starting the week of April 3, will enable the public to learn about the Low Dose Vasopressin Trauma Trial and an exception to informed consent needed to conduct this study with patients in shock.

Sponsored by the U.S. Navy, the study will involve approximately 500 shock patients over a 2-3 year period. Participants will be randomized to receive either low dose Vasopressin or the current standard of care (intravenous saline) while they are en route to the trauma center or immediately upon arrival.

Shock causes the patient's blood pressure to become dangerously low and the lack of blood-carrying oxygen to the body's organs can cause them to have difficulty functioning and potentially stop working. Currently, patients in shock immediately receive saline solution. Once at the hospital they may also receive additional medication, blood products and/or go to the operating room. The delivery of excessive fluids and blood products can cause respiratory failure; severe swelling and tissue damage

-more-

in the brain, abdomen, arms and legs; bleeding and clotting disorders; and infections. The goal of the Vasopressin study is to better understand how to reduce these complications and related deaths.

Vasopressin is a drug approved by the Food and Drug Administration (FDA) for patients with Diabetes Insipidus (extreme thirst and frequent urination) and for patients with abdominal swelling after surgery. It is also commonly used for other problems not currently approved by the FDA. These "off label" uses include treatment for heart attack patients and as an alternative drug for patients in shock. Vasopressin has been shown in previous studies to decrease the amount of fluid required to treat shock, so giving it to shock patients rapidly may decrease the likelihood of side effects from excessive fluids and may potentially increase survivability.

Because severely injured patients enrolled in the trial will be unable to give informed consent prior to enrollment, the study will use 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. 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. Community meetings will be held in San Antonio and throughout the 22-county South Texas region comprising Texas Trauma Service Area P. Notices will be made of these meetings so all individuals interested in learning more and who wish to offer feedback may do so. Individuals may also request a wrist band to identify them as not wishing to be considered for enrollment.

Additional information is available by contacting the project coordinator at the UT Health Science Center Department of Surgery-Trauma, 7703 Floyd Curl, San Antonio, Texas 78229-3900 or by phone at (210)567-3623.



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*Researchers seeking community input on exception to informed consent*

**Community Meeting to be held Wed. April 12 in Floresville**

**(SAN ANTONIO – MARCH 30, 2006)** What are your odds of surviving a serious traumatic injury?

Not good if your body goes into shock. In fact, a third to a half of all trauma patients who go into shock die, and trauma is the leading cause of death in all Americans under the age of 45. Finding a better way to treat patients in shock is the goal of a study to be conducted by University of Texas Health Science Center at San Antonio (UTHSC) surgeons at the Level I trauma center at University Hospital.

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Additional information is available by contacting the project coordinator at the UT Health Science Center Department of Surgery-Trauma, 7703 Floyd Curl, San Antonio, Texas 78229-3900 or by phone at (210)567-3623.

**COMMUNITY MEETING PRESENTAION  
VASOPRESSIN STUDY**

**SEE ATTACHMENTS FOR:**

1. Slide presentation outline used during community meetings
2. Participant handout - Vasopressin Question and Answers
3. Participant meeting evaluations
4. Community meeting record

1  **Low Dose Vasopressin  
Trauma Trial**

Community Consultation

University Hospital  
And  
University of Texas Health Science Center at San Antonio

2  **Principal Investigator**

Stephen M. Cohn, M.D.  
University of Texas Health Science Center at San Antonio  
Department of Surgery  
7703 Floyd Curl Dr.  
San Antonio, TX 78229-3900  
(210) 567-5705

3  **Who is sponsoring the study and how many patients will be enrolled?**

The United States Navy awarded a research grant to the principal investigator  
Approximately 500 subjects will be enrolled in this study

4  **Study Purpose**

*To evaluate the use of low dose Vasopressin  
when given to severely injured patients in shock*

5  **What is Shock?**

- Internal organs don't receive enough oxygen and have difficulty functioning
- Life-threatening injury
  - Dangerously low blood pressure
  - Severe bleeding
- Might lead to death

6  **How do we treat Traumatic Shock?**

- Fluids
- Blood products
- Medications
- Surgery

7  **Standard of Care for Shock**

- 1 In the Helicopter
  - Fluids (Salt water)
  - Medication
- 2 Upon arrival to the Hospital

- Fluids (Salt water)
- Medication
- Blood products
- Surgery

## 8 Standard of Care Limitations

- Excessive fluids and blood products can cause:
  - Respiratory Failure
  - Severe swelling with possible tissue damage
    - Brain
    - Extremities
    - Abdomen
  - Bleeding and clotting disorders
  - Infections

## 9 Need for Improved Outcome

- The Center for Disease Control (CDC) lists trauma as the leading cause of death among Americans under age 45
- Thousands of trauma patients die each year
- Death due to shock 30%-50%

## 10 Need for Improved Outcome

- To better understand how to treat shock
- Determine ways to manage fluids after trauma

## 11 What is Vasopressin ?

Vasopressin is a drug approved by the Food and Drug Administration (FDA) for patients with:

- Diabetes Insipidus (extreme thirst and frequent urination)
- Abdominal distention after surgery

## 12

Vasopressin is commonly used for the treatment of other disorders not currently approved by the FDA.

The use of Vasopressin in this manner is referred to as “Off-Label”

## 13 Current Standard of Care

“Off-Label”

- The use of Vasopressin is recognized:
  - by the American Heart Association for use in the management of patients in cardiac arrest.
  - as a standard treatment for shock due to infection.

## 14 Vasopressin Experience

- In animal studies low dose vasopressin has been shown to decrease the amount of fluid required to treat shock
- Leads to improved outcomes
- Beneficial effects have been observed in human studies

15  Why Use Vasopressin?

To improve the survival of patients during and after shock

To understand the impact that Vasopressin has on the treatment of patients in shock following injury

16  Potential Benefits of Low Dose Vasopressin

- Increase the likelihood of survival
- Decrease the chance of developing side effects due to large amounts of fluid

17  FDA Review

- Stephen M. Cohn, M.D. received clearance to proceed with this study from the Food and Drug Administration (FDA)
- The FDA authorized the use of exception from informed consent requirements for this study

18  Patient Protection

The Institutional Review Board (IRB) is a group of medical, scientific, and nonscientific members of the community

- Reviews all proposals for research on humans
- Assures patient safety
- Monitors community feedback

19  Patient Protection

- The UTHSCSA IRB will decide whether or not to allow University Hospital to participate in the Low Dose Vasopressin trial **BASED ON SCIENTIFIC MERIT AND COMMUNITY FEEDBACK**
- An independent data monitoring committee will oversee the trial
- The FDA will be kept informed of the trial's progress

20  What is Informed Consent?

**A process by which patients make informed decisions about participating in research studies.**

21  Informed Consent

- Traditionally required for all research studies
- Research studies compare 2 treatments (standard vs. investigational)
- Doctors describe each of these potential treatments
- Patients are informed of the potential risks and potential benefits associated with each of these treatments
- Patients choose whether to participate in the study

22  What is Exception from Informed Consent?

**Patients are enrolled in a research study without giving their informed consent**

23 

A federal regulation (21 CFR 50.24), created in 1996, allows certain studies that meet the following criteria to use this exception

- *Patients' lives must be at risk*
- Available treatments are not satisfactory
- Patients are unable to give consent
- Potential risks are reasonable, participation in the research could provide a direct benefit (*increased survival*) to the patient
- The research could not be practicably carried out without an exemption

24  Consent Safeguards

- If possible, the patient or a legally authorized representative (LAR) can give consent before the patient is enrolled in the study
- If consent cannot be obtained before enrollment, frequent attempts will be made to contact the patient's LAR and family to describe the study

25  Consent Safeguards

*The patient, family members, or a legally authorized representative may decide to withdraw the patient at any time*

26  Trial Design: Prior to arrival up to Six hours after injury  
*Severely injured trauma patients will be randomly assigned to either one of two groups (like flipping a coin)*

*Control    Test*  
Placebo

27  Trial Design

 *Control*

“Vasofluid” Placebo

2 **Test**

“Vasofluid” Vasopressin

28 **Who Would Be Included?**

***Patients at risk of dying***

- Who have severe injuries
- Who are in shock
- Who are at least 18 years old

29 **Who Would Be Excluded?**

1

- Patients who are obviously pregnant
- Patients who have “non survivable” injuries

2

- Patients who require CPR
- Patients with known orders not to resuscitate

30 **Potential Risks of Vasopressin**

The risks of vasopressin are usually associated with the dose given.

Risks include:

- Paleness, sweating, shaky feeling, headache, dizziness, chest discomfort, irregular heart beat, and heart attack.
- Increase in urine output
- Unforeseen happenings

31 **Near Infrared Spectrometer (NIR)**

- FDA approved non-invasive device
- Measures tissue oxygenation
- Applied upon arrival to Emergency Room
- Monitored for 24 hours

32

33

34 **Heart Rate Variability (HRV)**

- Standard of care heart monitoring
- Routine heart rhythm will be analyzed by computer
- Heart rhythm information will be collected to evaluate how the heart responds to “Vasofluid”

35 **Risks of NIR and HRV**

1

**NIR**

- Localized skin irritation

2

**HRV**

- None
- Data collected as standard of care.

36  **If We Participate...**

- The results of the study will be revealed to the community after the trial has been completed
- Those who do not want to participate in the study can [wear a special bracelet] to exclude themselves

37  **Questions or Comments?**

# Low Dose Vasopressin Study

## Questions and Answers

### What is the purpose of this study?

To evaluate the effectiveness of Vasopressin in treating patients suffering from shock after a traumatic injury.

### What is shock?

Shock can occur when there is massive loss of blood and a dangerously low blood pressure. When shock occurs internal organs don't receive enough oxygen and have difficulty functioning. Death due to shock 30-50%.

### Why is this study important?

To try and improve the survival of patients during and after shock.  
To better understand the impact Vasopressin has on the treatment and management of patients in shock following severe injuries.

### What is the current standard of care?

In the helicopter patients routinely receive:

- Fluids (salt water)
- Medications

Upon arrival to the hospital patients routinely receive:

- Fluids (salt water)
- Blood products
- Medication
- Surgery

### What are the standard of care limitations?

Excessive fluids and blood products can cause:

- Respiratory failure
- Severe swelling of the brain, extremities, and abdomen resulting in possible tissue damage
- Bleeding and clotting disorders
- Infections

### What is Vasopressin®?

Vasopressin is approved by the U.S. Food and Drug Administration (FDA) for patients with metabolic disorders such as diabetes insipidus (extreme thirst and frequent urination) and abdominal distention (bloating) after surgery.

Vasopressin is commonly used for the treatment of other disorders not currently approved by the FDA. Vasopressin is recognized by the American Heart Association for its use in the management of patients in cardiac arrest and is commonly used to treat patients who are in shock. For the purpose of this study, we will be administering Vasopressin in the treatment of shock. The dose of Vasopressin to be used in this study is lower than what is given to patients in cardiac arrest or in patients with low blood pressure in the intensive care unit.

# Low Dose Vasopressin Study

## Questions and Answers

### How is this study designed?

Severely injured trauma patients determined to be in shock, (blood pressure less than or equal to 90) before arriving, upon arrival or for up to six hours after arrival will be randomized (assigned by chance, like flipping of a coin) to receive either Vasopressin (experimental group) or Placebo (salt water solution with no active medication) in addition to standard of care. Subjects will have an equal chance of receiving either Vasopressin or salt water. This is a double-blinded study which means neither the subject nor the study doctor will know which medication is being given. However, the study doctor can find out which treatment is being given in the case of a medical emergency.

### How long will the study last?

The study will be conducted for approximately two years  
Individual participation in this study will last no more than 30 days.

### Who will be included in the study?

Patients who are severely injured and at-risk of dying will be included in this study. They must be at least 18 years old and in shock.

### Who will be excluded from the study?

Patients who will not be enrolled in the study include those who:

- Are obviously pregnant
- Have "unsurvivable" injuries
- Require CPR
- Have known orders not to resuscitate

### What are the potential benefits of Vasopressin?

There is the potential to decrease the chance of developing side effects due to large amounts of fluid increase and increase the chance for survival.

### What are the potential risks of Vasopressin?

The risks of Vasopressin are usually associated with the amount of Vasopressin given. Side effects (risks) that have been reported in patients receiving Vasopressin include:

- paleness
- throbbing headache
- chest discomfort
- irregular heart beat
- heart attack
- shaky feeling
- shakes
- dizziness
- increase urine output
- unforeseen happenings
- abdominal (stomach) cramps
- passage of gas
- nausea
- vomiting

The exact percentage of patients experiencing these side effects is not known.

## **Low Dose Vasopressin Study Questions and Answers**

### **How will consent be obtained?**

In most if not all cases patients will not be able to provide informed consent to be in this study because of their injuries. Patients eligible for this study will be enrolled using the exception from informed consent.

### **What is an exception from informed consent?**

It is including people in research without first having their agreement or consent. Usually, only people who give their consent or whose next of kin give consent, are included in research. An exception from the informed consent requirement may be granted in emergency situations making it possible to conduct research even when consent is not possible due to the nature of the patient's injuries. Regulations established by the federal government specify the conditions under which research can be done with an exception from consent.

### **What if patients don't want to participate in this study?**

Patients, and their legally authorized representatives or family members, will be notified at the earliest opportunity. A patient may withdraw or be withdrawn from the study at any time. Those who do not want to participate in the study can wear a special bracelet to exclude themselves. Contact 210-567-3623.

### **For further information, please contact:**

UT Health Science Center  
Department of Surgery – Trauma  
7703 Floyd Curl  
San Antonio, TX 78229-3900  
(210)567-3623

### **Internet information:**

If this study is approved, the study will be registered on the ClinicalTrials.Gov website ([www.clinicaltrials.gov](http://www.clinicaltrials.gov)).

## ESTUDIO DE BAJA DOSIS DE VASOPRESSIN PREGUNTAS Y RESPUESTAS

### ¿Cuál es el propósito de este estudio?

Evaluar el efecto del medicamento Vasopressin al tratar pacientes que sufren del estado de shock después de una lastimadura traumática.

### ¿Qué es shock?

Estar en estado de shock puede ocurrir cuando hay una cantidad grande de pérdida de sangre, y una peligrosa baja presión. Cuando esto ocurre los órganos internos no reciben suficiente oxígeno y tienen dificultad en funcionar. La muerte ocurre debido al estado de shock que 30-50 %.

### ¿Por qué es importante este estudio?

Es importante para tratar de mejorar la supervivencia de pacientes durante y después del estado de shock. Para entender mejor el impacto del medicamento Vasopressin que tiene en el tratamiento y manejo de estos pacientes que estén en estado de shock seguidos de severas lastimaduras.

### ¿Cuál es el actual cuidado estándar?

En los helicópteros los pacientes normalmente reciben:

- Fluidos
- Medicamentos

Al llegar a los hospitales los pacientes normalmente reciben:

- Fluidos (solución de agua salada)
- Productos de sangre
- Medicamentos
- Cirugía

### ¿Cuáles son las limitaciones del cuidado estándar?

Excesos de fluidos y productos de sangre pueden causar:

- Fallo respiratorio
- Severa hinchazón del cerebro, extremidades, y del abdomen como resultado de un posible daño a los tejidos
- Desórdenes en la pérdida de sangre y de coagulación
- Infecciones

### ¿Qué es Vasopressin?

El medicamento Vasopressin está aprobado por el U.S. Food and Drug Administration (FDA) para los pacientes con desorden del metabolismo como Diabetes Insípida (exceso de sed y frecuencia en orinar) y distensión del abdomen (hinchazón) después de la cirugía.

El medicamento Vasopressin es usado comúnmente para tratar otros desórdenes no aprobados por el FDA. Vasopressin es reconocida por La American Heart Association para el uso en el manejo de pacientes con paro cardíaco y usada comúnmente para tratar pacientes en estado de shock. El propósito de este estudio será administrar Vasopressin para tratar pacientes que se encuentran en estado de shock. La dosis de Vasopressin que se usará en este estudio será más baja en la cual es dada a los pacientes con paro cardíaco o pacientes con baja presión arterial que se encuentran en la unidad de cuidado Intensivo.

## **ESTUDIO DE BAJA DOSIS DEVASOPRESSIN PREGUNTAS Y RESPUESTAS**

### **¿Cómo está diseñado este estudio?**

Pacientes con una severa lastimadura que esté en estado de shock (baja presión con 90 o menos) **antes de llegar o 6 horas de haber llegado serán escogidos al azar** (asignado por casualidad, como girar una moneda) para recibir ya sea el medicamento Vasopressin (del grupo experimental) o el Placebo (solución de agua salada sin medicamento) en adición del cuidado estándar. Los sujetos tendrán igual oportunidad ya sea el recibir cualquiera de los dos el Vasopressin o la solución de agua salada. Este estudio es doble-ciego significa que ni el sujeto ni el doctor del estudio sabrán el medicamento dado. Sin embargo, el doctor del estudio podrá darse cuenta a cuál tratamiento se le estará dando en un caso de emergencia médica.

### **¿Cuánto durará este estudio?**

Este estudio será conducido por aproximadamente dos (2) años. La participación individual en este estudio no durará más de 30 días.

### **¿Quién será incluido en este estudio?**

Los pacientes que se encuentren severamente lastimados en riesgo a morir serán incluidos en este estudio. Tendrán que tener por lo menos 18 años y en el estado de shock.

### **¿Quién será excluido del estudio?**

Pacientes que no podrán ser incluidos en este estudio son:

- Obviamente las de estado de embarazo
- Pacientes con lastimaduras fatales
- Que requieren CPR
- Tienen órdenes de no resucitar.

### **¿Cuál es el beneficio potencial del uso de Vasopressin?**

Existe un beneficio potencial es la de disminuir la probabilidad de desarrollar efectos secundarios (riesgos) debido a la gran cantidad de fluidos y el aumento a la probabilidad de sobrevivir.

### **¿Cuáles son los riesgos potenciales de Vasopressin?**

Los riesgos de Vasopressin son asociados a la cantidad de Vasopressin dada. Los riesgos (efectos secundarios) que se han reportado en pacientes que reciben el medicamento incluyen:

- |                                 |                       |                             |
|---------------------------------|-----------------------|-----------------------------|
| • Palidez                       | • Tembloroso          | • Retorcijones del estómago |
| • Dolor de cabeza               | • Mareos              | • Pasaje de gas             |
| • Molestia en el pecho          | • Aumento de orín     | • Náusea                    |
| • latido irregular del corazón. | • eventos inesperados | • Vómito                    |
| • Ataque al corazón             |                       |                             |

El porcentaje exacto de pacientes que padecen de estos riesgos (efectos secundarios) no se sabe.

### **¿Cómo será obtenido el consentimiento?**

En muchos de los casos los pacientes no podrán dar el consentimiento por lo serio de las lastimaduras. Pacientes elegibles para este estudio serán inscritos usando la excepción del documento de consentimiento.

**ESTUDIO DE BAJA DOSIS DEVASOPRESSIN  
PREGUNTAS Y RESPUESTAS**

**¿Qué es la excepción del documento de consentimiento?**

Esta incluye a personas en el estudio sin tener primero su acuerdo o consentimiento. Usualmente, solo personas que dan consentimiento o los que tienen a un familiar que esté de acuerdo son incluidos en el estudio. El requisito an la excepción del documento del informe de consentimiento podrá ser concedido en situaciones de emergencia haciendo posible conducir el estudio aún cuando el consentimiento no fue posible obtenerse debido a las lastimaduras del paciente. Los reglamentos establecidos por el gobierno federal especifican las condiciones bajo la cual el estudio se podrá hacer con la excepción del documento de consentimiento.

**¿Qué pasa si el paciente no quiere participar en el estudio?**

Los pacientes y su representante legal autorizado o un miembro familiar serán notificados oportunamente. El paciente puede retirarse o podrá ser retirado de este estudio en cualquier momento. Aquellos pacientes que no quieran participar en el estudio usarán una pulsera especial para excluirlos del estudio. Favor de contactarse al # 210-567-3623.

Para más información por favor contáctese al:

UT Health Science Center  
Department of Surgery-Trauma  
7703 Floyd Curl  
San Antonio, TX 78229-3900  
210-567-3623

Información de Internet:

Si este estudio es aprobado, este estudio será registrado en el ClinicalTrial.Gov website ([www.clinicaltrials.gov](http://www.clinicaltrials.gov)).

## MEETING EVALUATION

**PLEASE COMPLETE THIS EVALUATION FORM AND GIVE IT TO THE PRESENTERS BEFORE YOUR LEAVE. IT IS IMPORTANT THAT THE PEOPLE DECIDING WHETHER TO CONDUCT THE STUDY KNOW HOW YOU RESPOND TO THE INFORMATION PRESENTED. YOUR RESPONSES WILL BE USED TO DECIDE IF OR HOW THE STUDY IS CONDUCTED.**

1. Did the presentation help you to understand what this study is about?

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2. In your own words, describe the purpose of this study and how it will be conducted, as you understand it:

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3. Patients enrolled in this study will not be giving their informed consent before they become participants. Instead, your community is assisting in the approval of this study. Do you understand the reasons for this?

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4. Do you object to the enrollment of someone in this research study without his or her individual consent before the study begins?

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5. Do you feel it is acceptable to conduct the study?

Please circle:        Yes    or    No

Why or why not?

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**Complete this section only if you wish:**

Age: \_\_\_\_\_

Ethnic background: \_\_\_\_\_

Male: \_\_\_\_\_ Female: \_\_\_\_\_

## EVALUACIÓN DE LA JUNTA

POR FAVOR COMPLETE ESTE FORMULARIO DE EVALUACIÓN Y ENTRÉGUELA A LOS PRESENTADORES ANTES DE QUE USTED SE VAYA. ES IMPORTANTE PARA LA GENTE QUE DECIDE SI AL CONDUCIR EL ESTUDIO SEPAN CÓMO USTED RESPONDE A LA INFORMACIÓN PRESENTADA. SUS RESPUESTAS SERÁN USADAS PARA DECIDIR SI O CÓMO EL ESTUDIO SERÁ CONDUCIDO.

1. ¿Le ayudó la presentación a entender de qué se trata el estudio?

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2. En sus propias palabras, describa el objetivo de este estudio y cómo será conducido, cómo usted lo entiende:

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---

3. Los pacientes que se inscriban en este estudio no darán su consentimiento informado antes de que ellos sean participantes. En cambio, su comunidad asiste en la aprobación de este estudio. ¿Entiende usted las razones para éste?

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4. ¿Se opone usted a la inscripción de alguien en este estudio de investigación sin su consentimiento individual antes de que el estudio comience?

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5. ¿Siente usted que es aceptable conducir el estudio?

Por favor marque:  Si  No

¿Por qué si o por qué no?

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Termine esta sección solamente si usted desea:

Edad: \_\_\_\_\_

Origen étnico: \_\_\_\_\_

Hombre: \_\_\_\_\_ Mujer: \_\_\_\_\_

**COMMUNITY MEETINGS RECORD**  
**Vasopressin Study**

Date:

Time:

City:

Host Organization:

# of attendees:

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Comments from Attendees: (attach additional pages if necessary)

---

# of evaluation forms collected:

## **Vasopressin Meeting Evaluations**

### **Sample of Comments from Completed Evaluations**

4 evaluation completed in preferred language of Spanish

**1. Did the presentation help you to understand what this study is about?**

- Yes
- Yes- very nice presentation, useful in increasing understanding
- Yes, very clear

**2. In your own words, describe the purpose of this study and how it will be conducted, as you understand it:**

- To verify the effectiveness of using Vasopressin in treating patient's with traumatic injuries
- Trauma victims who qualify will randomly be placed into two groups- one group to receive Vasopressin and one placebo. To determine effectiveness of Vasopressin (low dose) in shock.
- Patients unable to give prior consent, FDA requires community approval for San Antonio community to participate.
- This is possible life saving procedure, seems to be an ethical study

**3. Patients enrolled in this study will be not giving their informed consent before they become participants. Instead, your community is being consulted about conducting this study. Do you understand the reasons for this?**

- Yes
- Yes- a double blind study
- Community meetings are held to inform the public
- Yes- difficult to impossible to obtain consent from the group involved-Low risk important to gather this information.
- Yes-
  - Comment: Do not approve of any study being done without the patient consent

**4. Do you object to the enrollment of someone in this research study without his or her individual consent before the study begins?**

- No-is an emergency
- No
- Yes
- No as long as consent is obtained as soon as possible
- If they can make a sound decision, I feel they should have the opportunity to make the decision, even if you have informed the surrounding communities. There are many travelers from distant areas that are not aware of this study.
- Somewhat, as long as the patient is mentally capable they need to be informed of what they are going to be involved in.

**5. Do you feel it is acceptable to conduct the study? Why or why not?**

**"Yes" comments:**

- Trauma efficacy needs updating
- Realize the importance of improving the chance of a person living
- Patient benefits
- Is important to improve survival

## **Vasopressin Meeting Evaluations**

### **Sample of Comments from Completed Evaluations**

- If this treatment can help in not only preserving life, but also quality of life, then it is an acceptable study.
- The benefits of administering this medication would be tremendous

**"No" comments:**

**UTHSCSA Department of Surgery On-Line Presentation**  
**VASOPRESSIN STUDY**

SEE ATTACHMENT FOR:

1. Web Based Study Presentation
2. Web Based Study Presentation Response

**TELEPHONE RESPONSE  
VASOPRESSIN STUDY**

**SEE ATTACHMENTS FOR:**

1. Telephone and e-mailed questions from the public; a log was created for the purpose of documenting any other comments or issues raised by the public. A total of thirteen such inquiries were made. The logs are attached.

**Summary**  
**Telephone, e-mail, and verbal inquires**

March 31, 2006

- Questions regarding-
  - Which hospitals will be conducting study
  - Will this be a nation wide study
  
- Requests for bracelets-
  - Caller does not like the use of drugs "Off-Label"
  - Caller just does not want to participate in research.
  - Caller has multiple allergies, does not want to have reaction to vasopressin
  - Caller does not want any additional treatment "I have DNR order"
  - Caller and Caller's husband both have heart disease, do not want to receive vasopressin "may make heart condition worse"
  - Caller does not want "experimental drug"
    - This term was used in March 31<sup>st</sup> SA Express Article. Caller educated on vasopressin "off-label" and FDA approved uses

March 3, 2006

- Inquiring as to the Kerville communtiy meeting presentation.
  - Topic, length of time

April 7, 2006

- Questions regarding informed consent.