



ROC Hypertonic Saline Trial Hypertonic Resuscitation following Traumatic Injury

FROM: Russell Dumire, MD, FACS, Program Director, General Surgery Residency Program
Thomas Helling, MD, FACS, Medical Director, Department of Surgery
James Gregory, MD, FACS, Medical Director SICU, Director General Surgery Clerkships
S. Lee Miller, MD, FACS, Director Trauma Services
Site Investigators, ROC Hypertonic Saline Trial

RE: Resuscitation Outcomes Consortium Research Studies

We wish to inform you of a research study to be conducted in our area for accident victims who suffer severe injury to their brain. Traumatic brain injury describes an injury to the brain so severe that death or long-term physical and mental disability results. For further details on this study, view our website: www.conemaguh.org

Memorial Medical Center's Trauma Services Department will soon be taking part in a National Institute of Health-sponsored, pre-hospital research study to decide whether hypertonic fluids (fluids with high concentrate of salt or with Dextran -- a sugar compound) are better than standard fluids (normal saline) routinely given to patients with serious head injuries. In this study, the only change to standard treatment for a severe head injury is that one of the first bags of fluid given will be the hypertonic fluid or hypertonic fluid with Dextran. Great effort has been made to combine the research with standard care provided by paramedics and nurses responding to the accident. All standard care will be delivered without any restrictions.

Why is this research necessary? What is potential benefit of the research?

Trauma accounts for 150,000 deaths in the United States each year, and is the leading cause of death for persons between the ages of 1 and 44 years. Most of these deaths occur in injured persons who are in shock (low blood pressure) or who have severe head injury. Improving the initial resuscitation (recovery) could improve survival and quality of life for thousands of injured persons as well as reducing long-term disabling effects.

This research study compares the effects of normal saline (0.9% salt water, NS) to hypertonic saline (7.5% salt water, HS) alone or hypertonic saline with Dextran (a sugar compound, HSD) in traumatic brain injury. We want to know if hypertonic saline with or without Dextran improves the outcomes in victims of severe brain injury.

What is the regulatory basis for research in emergency situations?

Under normal conditions, all persons who participate in research provide their consent to take part in the research. Because this study will take place in an emergency situation, subjects will not be able to give consent or have a family member with them that can give consent on their behalf. Therefore, we will use the procedures provided by federal regulations for exemption of consent for research in an emergency situation. For more information on this regulation visit <http://www.fda.gov/oc/ohrt/irbs/except.html> and http://www.fda.gov/ora/compliance_ref/bimo/err_guide.htm.

Who is the Resuscitation Outcomes Consortium (ROC)?

ROC is a consortium(group) formed by the National Institutes of Health / National Heart, Lung and Blood Institutes (NHLBI) to perform clinical trials of therapies in order to improve survival from cardiac arrest and severe trauma. ROC includes 10 Regional Clinical Centers selected for experience and excellence in out-of-hospital research and care, as well as a Data Coordinating Center in Seattle, WA. Locally, this research is organized at Memorial Medical Center, in cooperation with the University of Pittsburgh and UPMC Health System. The University of Pittsburgh is one of the ten ROC centers.

What safeguards are in place?

The proposed research has been extensively reviewed by a Protocol Review Committee and an independent Data Safety Monitoring Board formed by the National Heart Lung and Blood Institute (NHLBI) as well as by the Food and Drug Administration (FDA). In Pennsylvania, this project was reviewed by the Department of Health (in Harrisburg by Pennsylvania Emergency Health Services Council and regionally by Emergency Medical Services Institute). This research protocol was also reviewed by the Memorial Medical Center Institutional Review Board (IRB). The IRB is a group of people (some work in healthcare and some do not; a clergy member always takes part) who review and approve research with the goal of protecting the subjects who choose to take part. On-going review of the safety of the study will be conducted by the Data Safety Monitoring Board assembled by the National Heart Lung and Blood Institute.

Who will be enrolled in the study?

Subjects (patients) who have severe blunt head trauma, are unconscious, are age ≥ 15 years, weigh ≥ 110 pounds, have a systolic (first number in your blood pressure which is a measure of artery pressure when the heart is pumping blood out to the body) of at least 91, and have not chosen to opt out of the study. Information is given below on how to opt out of this study.

How will I know if I was enrolled in one of these trials?

The research team will notify all subjects or their legally authorized representatives (next of kin) as soon as possible after enrollment. A research team member will be able to answer any questions or address concerns during the study.

What if I do not want to be enrolled in a trial?

Options to make the research team aware that you do not want to be enrolled in this type of trial are offered. Contact the research study nurse at (814) 534-3452 to obtain an opt-out bracelet.

Will I need to do anything to continue in the research protocol?

No. The researchers or their staff will collect data for all subjects. There is no required testing or paperwork at the hospital. However, we would like to contact you at specific times after your injury. You and your parents must give permission for us to contact you.

Have these interventions been studied before?

Previous research results lead us to be hopeful, but it is not known if giving hypertonic fluids with or without Dextran results in overall improved survival, improved quality of life, and improved function.

What adverse effects or risks are associated with these interventions?

HS and HSD may raise blood levels of sodium (salt) but these increases usually resolve without treatment within 12-24 hours. The dextran component of HSD has been linked with allergic-like reactions in some patients without trauma. No reactions have been reported for trauma patients.

What if I have additional questions?

If you need more information, please contact the research study nurse at (814) 534-3452.