MACRO Research Newsletter
Your source for information about current clinical trials in your UPMC workplace

April 2014

EPR-CAT

Emergency Preservation and Resuscitation for Cardiac Arrest from Trauma

Cardiac arrest in trauma patients is usually caused by massive bleeding. There is not enough blood left in the body for the heart to pump. Standard care includes giving large amounts of fluids. In addition, surgeons frequently make an incision in the left side of the chest or open the sternum to perform open-chest cardiopulmonary resuscitation, repair any direct injuries to the chest, and clamp the aorta to try to keep as much blood as possible flowing to the heart and brain. Despite these aggressive efforts, less than 10% of patients survive because vital organs cannot tolerate more than a few minutes of no blood flow without suffering irreparable harm.

The EPR-CAT study is designed to test the feasibility of rapidly cooling trauma victims who have suffered a cardiac arrest from massive bleeding. Animal studies have shown that cooling could protect vital organs until surgeons have time to stop bleeding and restore normal blood volume. In order to do this, a tube is inserted into a large artery and ice-cold saline is flushed into the body. If possible, cardiopulmonary bypass (heart lung machine) is used to assist cooling. Once cooling is achieved, the patient is transported to the operating room where surgeons try to stop the bleeding and repair the injuries. Cardiopulmonary bypass is then used to restore blood flow to the whole body and rewarm the patient.

The University of Pittsburgh will serve as both the Coordinating Center and a site. Dr. Samuel Tisherman is the study Principal Investigator and Pete Adams is the study coordinator. Additional clinical sites may include the University of Maryland Shock Trauma Center, Massachusetts General Hospital, University of Arizona, and Oregon Health and Sciences University. This study is sponsored by the Department of Defense Telemedicine and Advanced Technology Research Center.

Follow the link below as Sam Tisherman, MD and Raquel Forsythe, MD review the steps of the procedure and talk about its potential to save lives.

http://www.youtube.com/watch?v=FiXEq76TY6s
Spotlight on a High Enrolling ICU: 6F/G

MACRO CRC’s have been busy enrolling in 6F/G!

Over the last three months they have enrolled 17 subjects in four of our research studies.

Patients in 6F/G have been enrolled in CMV (4), EUPHRATES (5), GLUCOSE (5) and GRAIL (3).
(See page 4, Actively Recruiting Studies for a more detailed description of each study)

A big thank you and extra applause to the 6F/G staff for the referrals and their hard work helping MACRO increase enrollment!!

UTILIZATION OF UNDERGRADUATE STUDENTS AS RESEARCH ASSISTANTS (RA’S) IN ACUTE CARE FACILITIES: WIN - WIN SITUATION!

Stacy Stull presented MACRO’s RA program at the ACRP 2014 Global Conference & Exhibition on April 26-29, 2014, in San Antonio, Texas.

UNDERGRADUATE STUDENTS AS RESEARCH ASSISTANTS (RA’s)
IN ACUTE CARE: A WIN-WIN SITUATION!

Stacy D. Stull MS, CCRC, Clinical Research Coordinator
Patrick J. Coppler, BA, CCRC, Research Specialist

PROBLEM - COORDINATOR COVERAGE TIME
Off hour coverage by Clinical Research Coordinators (CRCs) for study screening and research procedures is not financially feasible or available in most contract research organizations.

SHARED SOLUTION
• Inexpensive off hours coverage
• Enables 24/7 coverage for screening, enrollment, research procedures and data collection
• Allows coordination of research blood draws with early AM clinical draws, to minimize subject burden
• Offers early exposure to research concepts such as inclusion/exclusion criteria, informed consent and protocol compliance
• Opportunities for shadowing with medical personnel
• Bolsters resume by affording letters of recommendation from CRCs and in some instances medical professionals

PROBLEM - STUDENT RESEARCH EXPERIENCE
Undergraduate research positions that afford real clinical experience and exposure are not readily available at the University of Pittsburgh.

HOW TO MAKE IT WORK
• Students initially recruited by reaching out to university pre-med programs/clubs and medical school personnel for contacts. Continuing recruitment aided by recommendations from current undergraduate Research Assistant (RAs) for promising pre-med, pre-health students. RAs stay with the program an average of 2 years.
• Multilevel training: new RAs shadow experienced RAs and Coordinators; online GCP, HIPAA and research specific on-line module training; weekly continuing education meetings to present information on new studies and clarify ongoing studies.
• Dedicated CRC supervisor of RAs to oversee daily research needs and maintain quality. Administrative responsibilities may be delegated to RAs chosen for specific tasks: training and shift scheduling. RA access to shared computer storage location for active study screening logs. Email shift reports required by RAs to enhance shift to shift communication.

Supported by the Departments of Critical Care Medicine, Surgery and Emergency Medicine and the Clinical and Translational Science Institute of the University of Pittsburgh

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Upcoming Study

Prehospital Air Medical Plasma (PAMPer) trial: Opening on May 1st

PAMPer is a randomized study to compare people who received plasma to people who didn’t. Medical helicopters will be taking turns carrying the plasma.

This study is being done to see if giving a plasma transfusion early in the course of treatment would help lower mortality of severely injured patients that lose a lot of blood (hypovolemic shock).

Some information suggests that severely injured people who are given plasma (the liquid part of the blood) before coming to the hospital need fewer blood transfusions and have fewer complications while in the hospital.

The study will be conducted over 4 years. The University of Pittsburgh will serve as the Coordinating Center for this multi-center clinical trial. Participating sites include:

- MetroHealth Medical Center
- University of Louisville
- University of Pittsburgh
- University of Tennessee Health Science Center
- University of Texas Southwestern Medical Center
- Vanderbilt University

Fun Fact Recap

1/8/14 - MACRO would like to congratulate Mary Stefanick on her new position as Clinical Research Coordinator Manager. She will provide assistance and oversight with daily coordinator operations and be a resource to new coordinators. Congratulations Mary!!

1/24/14 - Since August 2013, Dr. Seymour and MACRO CTRA’s have enrolled a total of 805 subjects in the PIPeLINE study at Presbyterian and Mercy.

2/7/14 - Dr. Allan Wolfson, Sara DiFiore and MACRO CTRA’s are starting 2014 off with a bang! They have already enrolled six patients in the STONE study in January alone. Enrollment at UPMC opened in September 2013 – total subjects enrolled to date are twelve.

2/19/14 - The University of Pittsburgh is currently tied for first place nationwide for enrollment in the GRAIL study! MACRO has enrolled a total of sixteen subjects, and for 2014, three. Keep up the great work Dr. Gunn and MACRO CRC’s!

4/18/14 - Dr. Al-Khafaji and MACRO have moved UPMC into first place nationwide for enrollment in the ELAD study! Total subjects enrolled to date are twelve, there are 41 participating sites!
Actively Recruiting Studies

**Presby/Montefiore ICUs**
- **CMV** – A study to determine whether CMV reactivation impact outcomes in critically ill patients with sepsis due to blood stream infections.  
  PI – Nina Singh
- **ELAD** – Extracorporeal liver assist device for alcohol induced liver decompensation.  
  PI – Ali Al-Khafaji
- **EUPHRATES** – Endotoxin filtration using dialysis circuit for septic patients.  
  PI – Ivonne Daly
- **GLUCOSE** – A study that will help to develop a unique way to understand the fluctuations in glucose levels and to ultimately control these glucose levels in critically ill patients.  
  PI – Gilles Clermont
- **GRAIL** – A study for prevention of cytomegalovirus (CMV) in patients who have an established respiratory failure, including ALI, associated with either severe sepsis or trauma.  
  PI – Scott Gunn
- **ProDiuS** – A study to evaluate if taking diuretics in a standardized fashion could improve health outcomes in patients with cardiorenal failure or cardiorenal syndrome.  
  PI – Kelly Liang
- **ProGReSS AKI ConsequenceS** – A study looking at the long-term effects of sepsis with a focus on acute kidney injury and cardiovascular outcomes.  
  PI – John Kellum & Sachin Yende
- **RUBY** – A study to collect blood and urine samples to help identify and validate protein biomarkers of recovery from moderate or severe acute kidney injury (AKI).  
  PI – Ali Al-Khafaji

**Presby Emergency Department**
- **EPR-CAT** – Feasibility of Emergency Preservation and Resuscitation for Cardiac Arrest from Trauma.  
  PI – Samuel Tisherman
- **PAMPer** – A study to see if giving a plasma transfusion early in the course of treatment would help lower mortality of severely injured patients that lose a lot of blood (hypovolemic shock).  
  PI – Jason Sperry
- **POINT** – The study goal is to determine the safety and effectiveness of the combination of low-dose aspirin and clopidogrel (Plavix®) in reducing the risk of stroke, heart attacks and other complications in patients who have just had a TIA or minor ischemic stroke.  
  PI – Vivek Reddy
- **SHINE** – A two-arm, multicenter, randomized, prospective clinical trial designed to test the safety and efficacy of tight glucose management (glu 80-130mg/dL) via continuous infusion of insulin versus control therapy (glu <180mg/dL) via subcutaneous insulin injections in patients that present with hyperglycemia after an acute ischemic stroke.  
  PI – Lori Shutter
- **STONE** – The primary objective of this randomized multi-center study is to determine the effect of tamsulosin on the proportion of patients passing a kidney stone as determined by patient report.  
  PI – Allan Wolfson

**Mercy Emergency Department**
- **SHINE** – A two-arm, multicenter, randomized, prospective clinical trial designed to test the safety and efficacy of tight glucose management (glu 80-130mg/dL) via continuous infusion of insulin versus control therapy (glu <180mg/dL) via subcutaneous insulin injections in patients that present with hyperglycemia after an acute ischemic stroke.  
  PI – Lori Shutter

**Shadyside Emergency Department**
- **POINT** – The study goal is to determine the safety and effectiveness of the combination of low-dose aspirin and clopidogrel (Plavix®) in reducing the risk of stroke, heart attacks and other complications in patients who have just had a TIA or minor ischemic stroke.  
  PI – Vivek Reddy