COMBAT Research Study

This study is different than other research studies because it involves enrolling patients who cannot give consent and the treatment must be given immediately after injury. In order to do this research study without initial consent, we must inform and consult with the public through community outreach before this research study will be approved or started. Subjects will be enrolled into this study without their consent unless they have opt out items that can be easily seen.

Background

The Problem

Bleeding is the most avoidable cause of death in trauma patients. Up to one-third (1/3) of severely injured trauma patients cannot form clots and die from rapid and sudden blood loss. Patients need transfusion of the parts of blood, red blood cells (RBC) and plasma, to slow bleeding and restore blood volume. Plasma has the proteins needed to clot, which can be used up in trauma. Research suggests giving plasma earlier to trauma patients who have serious and life-threatening bleeding improves survival. AB-FP24 is the plasma product being used in this study. It is similar to fresh frozen plasma (FFP) but may have slightly lower levels of certain clotting proteins.

Objective

To determine if giving plasma to severely injured trauma patients during ambulance transport versus after arrival to the hospital will help reduce bleeding.

Current Standard of Care

Based on the Advanced Trauma Life Support Guidelines from the American College of Surgeons, the current standard of care for trauma patients is to give sterile saline (salt water) through the veins either at the scene or in the ambulance. When the patients arrive at the hospital, they are evaluated and are given blood products including red blood cell and plasma transfusions, if they are bleeding.

Study Duration

The COMBAT Research Study (Control of Major Bleeding After Trauma) will take place at Denver Health from March 2013 to March 2016.

Study Area

Patients transported by Denver Health Paramedics to Denver Health Medical Center may be eligible for participation in the study.

The Study Design

Eligible patients with major blood loss after severe trauma will be enrolled in the research study at the scene based on their heart rate and blood pressure. Once enrolled, they will be chosen at random to receive the standard treatment, normal saline (salt water), or experimental treatment, (AB-FP24) plasma as the first treatment fluid. After the first fluid, both groups will receive the same standard of care. Blood samples and clinical information will be collected throughout the hospital stay up to 28 days after injury.

Reason

The AB-FP24 plasma contains special proteins and clotting factors. This helps slow bleeding and increase blood volume, which, in the end, may improve survival.

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