

## Pre-hospital Air Medical Plasma (PAMPer) Trial

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**Background:** While care of the severely injured patient has improved over the last 10 years, patients can still have uncontrolled bleeding causing early death, organ failure and other complications. A key reason for uncontrolled bleeding is early coagulopathy (blood not clotting properly) which complicates severe injury. Many studies suggest that blood component (such as blood plasma) transfusion procedures that treat early coagulopathy after trauma center arrival, are related to lower death rates and less need for blood component transfusion. Care given before a patient arrives at a trauma center, including treating coagulopathy earlier, may lessen, or prevent, bleeding. This further lowers the need for blood transfusions and lowers the complications of severe injury.

### **Aims:**

1. To define the effect of giving 2 units of plasma during air medical transport on death rates in patients with shock due to bleeding, as compared to standard air medical care, which gives blood only.
2. To define the effect of plasma given before trauma center arrival on outcomes such as blood transfusion needs in the first 24 hours, the development of multiple organ failure, hospital-acquired infection, acute lung injury and transfusion-related acute lung injury.

**Study Group:** Severely injured patients with shock due to bleeding being transported by Vanderbilt Lifeflight, based in Clarksville TN, from the scene or from an outside hospital to the Vanderbilt Trauma Center.

**Study Design:** The study will be a 4 year, open-label, randomized trial (like a flip of the coin) at six level-1 trauma centers with busy helicopter programs. Severely injured patients, transported by medical helicopter, and who have shock due to blood loss, will get 2 units of plasma, in addition to standard of care, **or** standard air medical care alone. All patients enrolled in this trial will have blood drawn for clotting studies after arrival at the Trauma Center and 24 hours later.

**Consent:** This study will use the federal approved rules for “Exception from Informed Consent Requirements for Emergency Research” (21 CFR 50.24). These rules require consulting with the community, telling the public about the trial and its results, as well as telling patients or their legally authorized representative about the study as soon as possible after enrollment. If someone does not want to take part in this research study, an “opt out” bracelet is available by calling (615) 936-1213. If a patient or family member at the scene or the outside hospital says that they don’t want to take part in this study, the patient will not be enrolled. Also, patients may decide not to take part any further when they are told about their enrollment after they arrive at the Vanderbilt Trauma Center.

**Questions/Comments:** If you have questions or comments about this trial, please call the PAMPer Trial office toll-free at **(855)730-8140** or the Vanderbilt Trauma Research Program at **(615) 936-1213**.