

Traumatic Injury ...everyone is at risk!

Pragmatic,
Randomized
Optimal
Platelet and
Plasma
Ratios



Learn about PROPPR, a nationwide, FDA- approved, massive blood transfusion research study that may affect you or someone you know.

What is Massive Transfusion?

A Massive Transfusion or MT, occurs when traumatically injured patients arrive at LAC+USC Medical Center with severe bleeding that requires a large amount of blood product to be infused in order to save their lives. Blood product can be a combination of red blood cells, plasma and or platelets.

What is the PROPPR study?

The purpose of the PROPPR study is to learn which combination of blood products given to trauma patients during a Massive Transfusion will improve their survival. The two blood transfusion combinations are: a) 1 unit of red blood cells: 1 unit of plasma: 1 unit of platelets; or b) 2 units of red blood cells: 1 unit of plasma: 1 unit of platelets. Both combinations are in widespread clinical use across the United States.

Why do this study?

The knowledge gained from this study will likely change the way patients who are severely bleeding are transfused. The study may also help lower the amount of preventable deaths resulting from shock from severe blood loss.

Who will be included?

- People who are 15 years or older, and
- Traumatically injured and need a MT to save their lives

People who meet the entry criteria will be randomly enrolled, like flipping a coin, into one of the two study groups:

- Those that get a 1:1:1 ratio of Red blood cells to Fresh Frozen Plasma to Platelets
- Those that get a 2:1:1 ratio of Red blood cells to Fresh Frozen Plasma to Platelets

Everyone in the study will be given the standard medical care for traumatic injury. In addition, several blood samples will be taken to test how blood clots after a severe injury.

What are the benefits?

Because we do not know which treatment is best for treating MT patients, a person enrolled in the study may not benefit from being placed in one study group over the other. Based on the information we get from this study, people who have a MT in the future may benefit from what is learned from this study.

What are the risks?

A patient should not expect any extra risks from being in the study, as your injuries required that you receive a Massive Transfusion. The risks are the same whether or not you are in the study.

How is enrollment in PROPPR different from other studies?

Normally, researchers ask the patient, legal guardian or surrogate for consent before a patient is enrolled into a study. Because a patient with a serious injury will not be able to give consent when they arrive at LAC+USC, the surgeons will enroll patients into the study without getting consent. This is called, "Exception from Informed Consent" (EFIC). We will contact a legal guardian or surrogate as soon as possible to tell them about this study and get their permission for the patient to remain in the study. You can choose to drop out of the study at any time.

What is EFIC?

The U.S. Food and Drug Administration (FDA) is an agency of the federal government that oversees human research protection involving medicines and blood products. The FDA has created a set of special rules. Under EFIC, research studies in certain emergency situations can be conducted without consent.

EFIC can only be used when:

- The person's life is at risk, AND,
- The treatments we have don't work, AND
- The study might help the person, AND
- It is not possible to get permission:
 - from the person because of his or her medical condition nor
 - from the person's guardian because there is a very short amount of time required to treat the medical problem

Before researchers may do a study using EFIC, they must provide information about the study to the community and get their feedback.

Where can I learn more about the study and or share my opinions?

Before the study begins, study team members will be visiting the various colleges, Farmer's Markets and other community gatherings around LAC+USC to provide information, answer questions and get community members' thoughts and feelings about the study. You can also email or call the study team. There will also be information about the study in the media (for example, newspapers and radio).

Phone: 323-6960-USC
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What if I do not want to be included in the study?

If you decide you don't want to be included if you were injured, call us or send us an e-mail with your contact information and a bracelet with the words "PROPPR 0" will be sent to you. You will need to wear this bracelet at all times throughout the study period (about 2 years), or else you could be enrolled in the PROPPR study if you suffer a traumatic injury and are treated at LAC+USC. Cards for your wallet also exist, but your wallet may not be with you when you're taken to LAC+USC.

If you do not take part in the study, you will receive the standard medical treatment provided for traumatic injuries at LAC+USC.

R.O.C Network

LAC+USC is a satellite member of the Resuscitation Outcomes Consortium. The Resuscitation Outcomes Consortium (ROC) is the largest pre-hospital clinical research consortium in the world, focusing on research in the areas of pre-hospital cardiopulmonary arrest and severe traumatic injury.

The sponsors listed below have committed approximately \$10 million per year for at least 6 years in order to establish an infrastructure capable of conducting multiple collaborative trials to aid in the rapid translation of promising scientific and clinical advances aimed at improving resuscitation outcomes:

- The National Health, Lung and Blood Institute (NHLBI, the lead Federal Government sponsor of this program) and other Institutes within the National Institutes of Health (NIH)
- US Army Medical Research
- Canadian Defense Research and Development

Contact Us

PROPPR Study

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This study is approved by the USC Institutional Review Board (IRB)