



QUICKLINKS: VISITOR DIRECTORY MAPS CLINICS




Hospital 911 Medical Response Behavioral Health School-based Clinics Denver CARES
 Public Health Community Health Correctional Care Poison & Drug Center DH Medical Plan

Trauma Center

Center for Complex Fractures and Limb Restoration
 Colorado Biological, Nuclear, Incendiary, Chemical and Explosive (BNICE) Training Center
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Polyheme Trial

Questions and Answers Polyheme® Trauma Trial

How to obtain "No Participation" study bracelets

Study Approved by COMIRB

Upcoming Meeting Dates

Why is this study being conducted?

To evaluate the life-saving potential of PolyHeme® when given to severely injured & bleeding patients, starting at the scene of injury

What is the title of this study?

A Phase III, Randomized, Controlled, Open-Label Multicenter, Parallel Group Study Provisions for Exception from Informed Consent Requirements Designed to Evaluate and Efficacy of Poly SFH-P Injection [Polymerized Human Hemoglobin (Pyridoxylated) When Used to Treat Patients in Hemorrhagic Shock Following Traumatic Injuries in Prehospital Setting

What is the design of this study?

Patients in "hemorrhagic shock" will begin to receive either the standard of care (salt water [control]) or PolyHeme (experimental treatment). Treatment would begin before arrival at hospital, either at the scene of the injury or in the ambulance, and continue during the initial injury period in the hospital.

In the hospital, patients in the control group will receive salt water for hydration and necessary to boost oxygen delivery levels. Unlimited doses of each are allowed in the hospital.

Patients in the treatment group will receive salt water for hydration and PolyHeme® for oxygen delivery levels. The maximum dose of PolyHeme will be 6 units during the first 12 hours. Additional units may be used thereafter, if oxygen delivery levels need to be increased.

What is hemorrhagic shock?

Hemorrhagic shock means that the patient has experienced shock, secondary to massive blood loss.

Shock is a potentially life-threatening condition that includes:

- Dangerously low blood pressure
- Internal organs may not receive enough oxygen and therefore may not function
- Might lead to death

Why is there a need for improvement in the way trauma patients are treated in the hospital?

Trauma is the leading cause of death among Americans under the age of 45.

What is the current standard of care? How are trauma patients usually treated in the hospital?

They are given saline solution (salt water) at the scene or in the ambulance. When hospital, they are given blood after typing and cross-matching is accomplished.

Who would be eligible for the study?

Patients who have lost a large amount of blood and are in shock
Patients who are at least 18 years old
Patients who have sustained severe injuries

Who would be excluded from the study?

Women who are obviously pregnant
Patients with severe brain injuries
Patients who require CPR to maintain their heartbeat
Patients with "unsurvivable" injuries
Patients who are known to object to blood transfusions
Patients who are known to refuse resuscitation

What is PolyHeme®?

PolyHeme® is an oxygen-carrying blood substitute made from human blood. PolyHeme requires no cross-matching, therefore it is immediately available and compatible with all blood types. PolyHeme is highly purified to reduce the risk of viral disease transmission and has an extended shelf-life of over 12 months.

Is PolyHeme® safe?

In clinical trials to date, PolyHeme has demonstrated no clinically relevant adverse

Past studies have shown that PolyHeme carries as much oxygen as blood, has not caused damage, keeps people alive who have lost all of their own blood, and can be infused up to 10 times a person's entire blood volume.

Has PolyHeme® been tested on humans before?

There have been 5 human clinical trials of PolyHeme®.

How many people have received PolyHeme®?

Over 300 people have received PolyHeme® including patients in a hospital based trial.

What happened to them?

In the Phase II hospital trauma trial, PolyHeme significantly increased survival compared to historical controls.

What is an exception from informed consent?

Regulations established by the Federal government, (21 Code of Federal Regulations) specify the conditions under which an exception from informed consent may be used. In emergency situations, research can be carried out even when consent is not possible due to the nature and extent of the patient's injuries.

Why was such an exception granted in connection with this study?

Patients are in a life-threatening situation, available treatments are unproven or unproven, and the collection of valid scientific evidence is necessary to determine the safety and efficacy of particular interventions.

Participating in the study has the prospect of direct benefit to the enrolled patients because:

- Patients are in a life-threatening situation that necessitates intervention
- Previous studies demonstrate the potential to provide a direct benefit to enrolled patients
- Risks associated with the use of the experimental treatment are reasonable when compared to what is known about the patients' medical condition, the risks and benefits of standard therapy, if any, and the risks and benefits of the proposed intervention

It is expected that patients will be unable to give informed consent because the extent of injuries and the fact that they are in shock.

There won't be time to find and ask for consent from the patient's legally authorized representative (LAR) before beginning treatment.

Who grants such exceptions?

The U.S. Food and Drug Administration (FDA) under regulations called 21 Code of Federal Regulations 312.24 specifies the conditions under which an exception from informed consent can be obtained. The Institutional Review Board (IRB) associated with each institution grants such exceptions locally.

What if patients don't want to participate in this study?

Patients can withdraw from the study at any time by notifying the investigator.

Will patients still receive treatment if they don't want to participate in the study?

Patients will still receive the standard of care if they decline to participate in this study.

What are the potential benefits of participating in the study?

PolyHeme® may increase the likelihood of survival after traumatic injury.

Patients might avoid the risks of blood transfusion.

Patients might avoid a reduction in the function of internal organs that sometimes occurs with blood transfusion.

This study may help patients in the future.

What are the potential risks of participating in the study?

Rash

Increased blood pressure

Kidney or liver damage

Transmission of hepatitis and HIV viruses

Unforeseen happenings

How much will it cost patients to participate?

There is no charge to the patient to participate in this study. The costs of certain lab tests that are required will be paid by the study sponsor.

Will patients get paid to participate?

No, patients will not be paid to participate in this study.

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Who is the manufacturer of PolyHeme®?

Northfield Laboratories Inc., Evanston, IL. For more information, visit www.northfield.com

For further information, or if you have comments or questions please contact:

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Upcoming Meeting Dates

No meetings currently scheduled.

"No Participation" Study Bracelets

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