



## PolyHeme® Trauma Trial

### Community Consultation

Lehigh Valley Hospital  
Trauma & Critical Care Research  
610-402-CARE  
www.lvh.org

8/18/03

## Clinical Investigator

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  - Medical Director, Surgical Intensive Care Unit-Lehigh Valley Hospital
  - Director of Research- Department of Surgery-Lehigh Valley Hospital

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## Study Sponsor

Northfield Laboratories Inc.

- Developer of the oxygen-carrying blood substitute called PolyHeme®
- Conducted multiple studies with PolyHeme over the past decade
- Most studies have been with injured trauma patients
- Company website: [www.northfieldlabs.com](http://www.northfieldlabs.com)

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## Study Purpose

*To evaluate the life-saving potential of PolyHeme® when given to severely injured and bleeding patients in "hemorrhagic shock," starting at the scene of injury*

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## What is Hemorrhagic Shock?

**Hemorrhagic:** massive loss of blood

**Shock:** life-threatening condition

- Dangerously low blood pressure
- Internal organs don't receive enough oxygen and have difficulty functioning
- Might lead to death

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## Need for Improved Outcome

- The Center for Disease Control (CDC) lists trauma as the leading cause of death among Americans under age 45
- Thousands of trauma patients die each year
- Many of these patients die because the "standard of care" cannot reverse the damaging effects of hemorrhagic shock

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## What is the Standard of Care?

*Represents the current treatment*

### *In the Ambulance or Helicopter*

The patient receives salt water (blood is not available)

### *In the Hospital*

The patient receives salt water and donated blood

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## Standard of Care Limitations

### *In the Ambulance/Helicopter*

- Salt water does not carry oxygen, unlike blood
- Without enough oxygen, the body and its internal organs have difficulty functioning and can stop working (organ failure)

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## Standard of Care Limitations

### *In the Hospital*

- Donated blood takes time (45-60 minutes) to be matched for each patient
- Patients who receive more than 6 units of donated blood in the first 12 hours have an increased risk of organ failure

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## What is PolyHeme®?

*A blood substitute that carries oxygen*

1 unit of PolyHeme  
=  
1 unit of blood



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## What is PolyHeme®?

- Made from human blood
- Compatible with all blood types
- Immediately available
- Reduced risk of viral disease (viral load reduced over a billion times)



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## Why Use PolyHeme®?

- PolyHeme was developed to treat blood loss when blood is not available
  - Blood is not available in the ambulance
  - PolyHeme will be immediately available in the ambulance and carries oxygen
- PolyHeme can reduce the use of donated blood in the first 12 hours after injury, and might avoid potential organ failure

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## Why Use PolyHeme®?

*To improve survival  
of severely injured and bleeding  
patients*

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## PolyHeme® Experience

- PolyHeme has been studied in more than 300 individuals and 5 different clinical trials
- PolyHeme has been extensively studied in hospitalized trauma patients
- *PolyHeme has kept trauma patients alive when they have lost all of their own blood*

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## PolyHeme® Experience

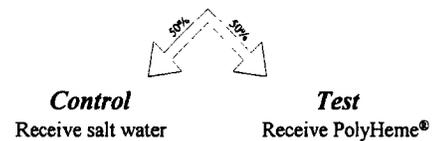
Past studies have shown that PolyHeme

- Carries as much oxygen as blood (1 unit of PolyHeme = 1 unit of blood)
- Reduces need for donated blood
- Has not caused organ damage
- Has replaced up to two times a person's entire blood volume (2 x 10 units = 20 units)

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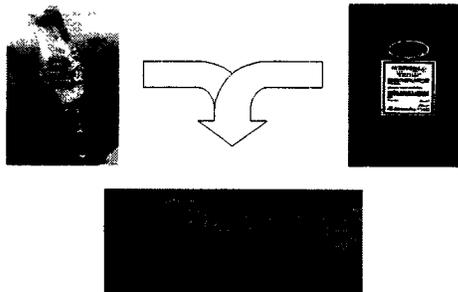
## Trial Design: Before the Hospital

*Severely injured trauma patients will be  
assigned to either one of two groups  
by chance*



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## Ambulance Infusion



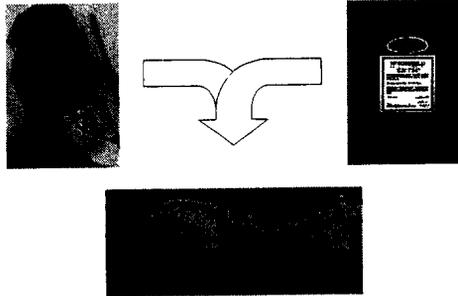
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## Trial Design: At the Hospital

- | <i>Control</i>                         | <i>Test</i>                                     |
|--|---|
| • Salt water for hydration             | • Salt water for hydration                      |
| • Donated blood to boost oxygen levels | • PolyHeme® to boost oxygen levels              |
|  | • Maximum dose of 6 units during first 12 hours |
|  | • Donated blood will be used thereafter         |

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## Hospital Infusion



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## Who Would Be Included?

### *Patients at risk of dying*

- Who have sustained severe injuries
- Who have lost a large amount of blood and are in shock
- Who are at least 18 years old
- Who are of either gender (male or female)

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## Who Would Be Excluded?

- Patients who are obviously pregnant
- Patients who have severe head or brain injuries
- Patients who have "unsurvivable" injuries
- Patients who require CPR
- Patients with known objections to blood transfusions
- Patients with known orders not to resuscitate

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## FDA Review

- Northfield Laboratories received clearance to proceed with this study from the Food and Drug Administration (FDA)
- The FDA authorized the use of an exception from informed consent requirements for this study

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## What is Informed Consent?

A process by which patients make informed decisions about participating in research studies

- Traditionally required for all research studies
- Research studies compare 2 treatments (standard vs. investigational)
- Doctors describe each of these potential treatments

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## What is Informed Consent?

A process by which patients make informed decisions about participating in research studies

- Patients are informed of the potential risks and potential benefits associated with each of these treatments
- Patients choose whether to participate in the study

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## What is Exception from Informed Consent?

***Patients are enrolled in a research study without giving their informed consent***

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## How Can That Be?

A federal regulation (21 CFR 50.24), created in 1996, allows certain studies that meet the following criteria to use this exception

- *Patients' lives must be at risk*
- Available treatments are not satisfactory
- Patients are unable to give consent
- Potential risks are reasonable

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## How Can That Be?

A federal regulation (21 CFR 50.24), created in 1996, allows certain studies that meet the following criteria to use this exception

- Participation in the research could provide a direct benefit (*increased survival*) to the patient
- The research could not be practicably carried out without an exemption

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## Consent Safeguards

- If possible, the patient or a legally authorized representative (LAR) can give consent before the patient is enrolled in the study
- If consent cannot be obtained before enrollment, frequent attempts will be made to contact the patient's LAR and family to describe the study

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## Consent Safeguards

***The patient, family members, or a legally authorized representative may decide to withdraw the patient at any time***

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## Potential Benefits of PolyHeme®

- *Might increase the likelihood of survival*
- Can enhance the amount of vital oxygen in the patient's blood
- Is compatible with all blood types
- Is immediately available
- Has reduced risk of viral disease (viral load reduced over a billion times)

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## Potential Risks of PolyHeme®

- Rash
- Increased blood pressure
- Kidney or liver damage
- Viral infection (HIV, hepatitis, etc.)
- Unforeseen happenings

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## Patient Protection

The Lehigh Valley Hospital Institutional Review Board (IRB) is a group of medical staff, scientific, and nonscientific members of the community

- Reviews all proposals for research on humans
- Assures patient safety
- Monitors community feedback

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## Patient Protection

- The IRB will decide whether or not to allow this hospital to participate in the PolyHeme® trial
- An independent data monitoring committee will oversee the trial
- The FDA will be kept informed of the trial's progress

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## If We Participate...

- The results of the study will be revealed to the community after the trial has been completed
- Those who do not want to participate in the study can [wear a special bracelet] to exclude themselves

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Questions  
or  
Comments?

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