

Mayo Clinic
Rochester, MN

Community Notification Meeting Plan

PolyHeme® Trauma Study

Draft 1, 10/01/2003

About Mayo Clinic and the PolyHeme® Trauma Study

Mayo Clinic has been chosen to participate in a national clinical trial to evaluate the safety and efficacy of an oxygen-carrying blood substitute called PolyHeme®, in increasing survival of critically injured and bleeding patients. Our goal is to compare the survival rate of patients receiving PolyHeme® to that of patients who receive the current standard of care, which is saline solution (salt water).

This research study will launch in the fall of 2003. The participation goal is to enroll 40 men and women over the age of 18 who are severely injured, bleeding and in shock.

Purpose of Community Notification Meeting Plan

The IRB is an independent body composed of medical, scientific, and nonscientific members, whose responsibility is to ensure the protection of the rights, safety, and well being of patients enrolled in clinical trials. The traditional IRB approval of a clinical trial includes a requirement that informed consent be obtained from patients before enrollment can occur. Under special circumstances and in accordance with federal regulations, the IRB responsible for the review, approval and continuing monitoring of a clinical trial may give approval for patient enrollment in trials in emergency situations without requiring informed consent, provided specific criteria are met. These criteria include: patients must be in a life-threatening situation, the experimental treatment must offer patients the potential for direct clinical benefit in the form of increased survival, the risks are reasonable, and the research could not be conducted without the exception from informed consent.

Components of the Trial

Patients in "hemorrhagic shock" will begin to receive either the standard of care (crystalloid) (control) or PolyHeme (investigational treatment).

Treatment would begin before arrival at the hospital, either at the scene of the injury or in the ambulance.

In the hospital, patients in the control group will receive crystalloid and/or blood as necessary for resuscitation. Unlimited doses of each are allowed.

Patients in the treatment group will receive crystalloid and/or PolyHeme® as necessary for resuscitation. The maximum dose of PolyHeme will be six units during first 12 hours. After 12 hours or after the patient has received six units of PolyHeme®, treatment will be as in the control group.

Spokesperson(s)

Andy Boggust, M.D. a Mayo Clinic Emergency Medicine physician and principal investigator at Mayo is the primary spokesperson. Secondary spokespersons are Daniel Hankins, M.D. a Mayo Clinic Emergency Medicine physician, and Scott Zietlow, a Mayo Clinic surgeon specializing in trauma care.

Key Messages

④ ***The PolyHeme Trauma Study is important because:***

The results of prior clinical trials indicate that PolyHeme® may increase survival in severely injured and bleeding patients by providing early oxygen-carrying capacity when blood is not available.

The use of PolyHeme in these settings has the potential to address a critical unmet medical need for an oxygen-carrying solution where blood is currently not available.

④ ***It's important to participate in this study because:***

We are in need of new methods to treat trauma patients in the absence of blood.

④ ***It's important to provide feedback on these meetings***

④ ***Anyone can elect not to participate in this study.***

Patients who wish to be excluded from this study can do so by wearing identifying wrist bands which will be provided by the sponsor, Northfield Laboratories, Inc.

Wrist bands are available by:

Contacting Northfield Laboratories directly

Contacting the investigators

Coming to community meetings

Key Audiences

All residents of Olmsted County

All residents of surrounding counties served by Mayo One

Jehovah's Witness community

Meeting Frequency and Proposed Agenda

The purpose of the community notification meetings is to create understanding and awareness to the general public who may be potential research participants. The primary concentration of these meetings will occur within Olmsted County and will include Rochester (to be held at John Marshall, Mayo and Century High Schools), Kasson, Byron, Stewartville, Eyota, St. Charles, Pine Island, Plainview. Potential cities include Owatonna, Austin, Albert Lea, Winona. Additional meetings will be scheduled with the assistance of the Intercultural Mutual Assistance Association, the Diversity Council, and

Mayo Clinic's Office of Diversity to serve the non-English speaking community members that may be affected.

See attached Sample Meeting agenda.

See attached Sample Feedback Form for Participants.

See attached Sample Questions and Answers.

Meeting Attendees

In addition to the principal investigator, members of the IRB, Division of Communications, Center for Patient Oriented Research, and additional study staff will be required to attend each meeting.

Media and other Communications Tactics

It is important to note that these tactics will not be used to recruit, but to increase awareness about the study amongst potential candidates in an attempt to create understanding prior to potential study enrollment.

④ Internal

Produce brochure and flyer with key points about this study. **See attached Sample Questions and Answers.**

Distribute brochure and flyer to community via public meetings
Departments of Surgery, Anesthesiology, Emergency Medicine and Critical Care Nursing will attend presentation by the Principal Investigator. In addition, this presentation will be videotaped, and made available for distribution to all employees as reference. For those unable to attend, information will be made available by study personnel attending department meetings.

Mayo Medical Transport will execute in-services for each paramedic/flight nurse potentially involved in the trial. Paramedic Education Specialist and principal investigator will carry out this education process.

④ External/Media

Issue news release to regional media list. **See Sample Media Advisory – News Conference and Community Meeting**

Distribution of mass mailing from Dr. Boggust announcing the trial and a list of meeting times and places

Distribute notice for house of worship bulletins **See Sample for House of Worship Bulletins**

Pitch story to Jeff Hansel, Post-Bulletin

Pitch story to Rick Reynolds , KTTC-TV, and Gary Peterson/Carla Johnson, KAAL-TV

Pitch story with local angle to media in nearby communities that have Mayo tie, i.e. LaCrosse-Terry Rindfliesch; Eau Claire- health reporter.

Pitch story to Erin Galbally, Minnesota Public Radio's health talk program.

Pitch story to Maura Lerner, Minneapolis Star Tribune, or Tom Majewski, St. Paul Pioneer.

Pitch story to Dennis Douda, WCCO-TV. Same for KARE-TV.

Create a 30-second public service announcement to be aired on selected stations.

A series of specially coordinated public meetings.

Special mayo.edu email address. All correspondence can be reviewed and responded to by both the investigator and IRB. All correspondence will be persistent with only the exchange administrators have the right to delete correspondence.

Clinical Trials webpage at mayoresearch.mayo.edu to contain the study title and information listed in **See Sample Questions and Answers.**

④ *Other communications opportunities*

Needs to Implement Communications Plan

Finalize communications plan and tactics

Develop timelines for tactics

Assign responsibilities

Designate secondary spokespersons

Determine and create collateral communications materials

Identify key organizations and people for targeted audiences

Chronology of Events

It is recommended that the above tactics follow this chronology:

Distribute invitation to community meeting, news release and mass mailing

Meetings with Mayo Medical Transport, Departments of Surgery, Anesthesiology, Emergency Medicine and Critical Care Nursing

Web page goes live

Run paid Public Notice

Conduct media outreach

Distribute follow-up media advisory

Confirm media attendance

Conduct community meeting(s)

Distribute optional materials:

Study description

Exception from informed consent regulations

Clinical article reprints

Feedback form for participants

Document news coverage, public response

Report findings to IRB

SAMPLE AGENDA FOR COMMUNITY MEETING

AGENDA

POLYHEME® TRAUMA TRIAL COMMUNITY MEETING

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

-
- | | |
|----------|---------------------------------|
| 10:00 am | Refreshments and Registration |
| 10:15 am | Welcome and Introductions |
| 10:20 am | Federal regulations and the IRB |
| 10:30 am | Explanation of PolyHeme® trial |
| 10:45 am | Questions and Answers |
| 11:30 am | Adjourn |

Handouts are available at the back of the room.

SAMPLE FEEBACK FORM FOR PARTICIPANTS

Community Consultation
LOCATION OF MEETING
DATE OF MEETING

Please circle your answers

1. Would you support a study such as the one described at this meeting being conducted in this community, specifically, a study in which severely injured and bleeding patients would be enrolled without giving their informed consent?

Yes No

2. If you were severely injured and bleeding and were being treated by the paramedics in your community, would you want to be enrolled in this type of study?

Yes No

3. If a family member of yours were severely injured and bleeding and were to be treated by the paramedics, would you want him or her to be enrolled in this type of study?

Yes No

4. Do you have any comments or concerns you wish to share with the investigators?

Age: _____ Ethnic background: _____

Gender: Male _____ Female _____

Thank you for your participation today.
If you have any other questions please contact:
Andy Boggust, M.D.
200 First St. SW
Rochester, Mn 55902
(507) 284-2511
Email address

QUESTIONS AND ANSWERS POLYHEME® TRAUMA TRIAL

Why is this study being conducted?

To evaluate the life-saving potential of PolyHeme® when given to severely injured patients and 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 Using Provisions for Exception from Informed Consent Requirements Designed to Evaluate the Safety and Efficacy of Poly SFH-P Injection [Polymerized Human Hemoglobin (Pyridoxylated) PolyHeme®] When Used to Treat Patients in Hemorrhagic Shock Following Traumatic Injuries Beginning in the 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 (investigational treatment). Treatment would begin before arrival at the hospital, either at the scene of the injury or in the ambulance, and continue during a 12 hour postinjury period in the hospital.

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

Patients in the treatment group will receive salt water for hydration and PolyHeme® to boost oxygen levels. The maximum dose of PolyHeme will be 6 units during first 12 hours. Blood will be used thereafter.

What is hemorrhagic shock?

*Hemorrhagic means the patient has experienced massive blood loss
Shock is a life-threatening condition that might include:*

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

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

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?

They are given saline solution (salt water) at the scene or in the ambulance. When they arrive at the hospital, they may be given blood before or 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. It has an extended shelf-life of over 12 months.

Is PolyHeme® safe?

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

Past studies have shown that PolyHeme® carries as much oxygen as blood, has not caused organ damage, keeps people alive who have lost all of their own blood, and can be infused up to two 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 patients have been treated with PolyHeme®?

Over 300 patients have been treated, including patients in a hospital-based trauma trial.

What happened to them?

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

What is an exception from informed consent?

Regulations established by the Federal government, (21 Code of Federal Regulations 50.24) specifies the conditions under which an exception from informed consent so that in emergency situations, research can be carried out even when consent is not possible because of the nature and extent of the patient's injuries.

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

Patients are in a life-threatening situation, available treatments are unproven or unsatisfactory, and the collection of valid scientific evidence is necessary to determine the safety and effectiveness 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 PolyHeme® are reasonable in relation to what is known about the patients' medical condition, the risks and benefits of standard therapy, 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 their 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 50.24 specifies the conditions under which an exception from informed consent may be obtained. The Institutional Review Board (IRB) associated with each hospital approves its use locally.

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

Patients will be excluded from the study by wearing a wristband which identifies their desire not to participate. These wristbands are available from the following locations:

- 1. Directly from the sponsor, Northfield Laboratories, Inc, please refer to the contact information below.*
- 2. By contacting any of the investigators in this study by mail, e-mail, or by telephone. Please refer to the contact information listed below*

3. *By attending any of the scheduled community meetings.*

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 follows 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 laboratory 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.

Who is the manufacturer of PolyHeme®?

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

SAMPLE MEDIA ADVISORY – NEWS CONFERENCE

**HOSPITAL NAME CHOSEN TO STUDY INVESTIGATIONAL BLOOD
SUBSTITUTE IN TRAUMA PATIENTS**

WHAT: NEWS CONFERENCE

Learn about a ground-breaking national clinical research study that may be conducted at St. Marys Hospital.

Andy Boggust, M.D., Consultant, Department of Emergency Medicine will present the details of the study protocol, which includes an exception from informed consent requirements. He will also be available for interviews at the conclusion of the presentation.

WHEN: DAY, DATE, TIME

WHERE: HOSPITAL NAME, ADDRESS, ROOM

BACKGROUND: St. Marys Hospital will be one of a select number of Level I trauma centers in the country to study PolyHeme®, an oxygen-carrying blood substitute, and its ability to increase survival in critically injured and bleeding patients. Treatment would begin before arrival at the hospital, either at the scene of the injury or in the ambulance, and continue through a 12 hour post injury period in the hospital.

According to the CDC, trauma-related injuries are a leading cause of death among Americans under 45 years old, affecting over 2 million persons per year. Nearly one in five trauma victims dies as a result of his/her injuries.

PolyHeme® is a universally compatible, immediately available, oxygen-carrying resuscitative fluid designed to treat hemorrhagic shock where blood transfusion is required but blood is not available.

HOSPITAL BOILERPLATE

SAMPLE MEDIA ADVISORY – COMMUNITY MEETING

MAYO CLINIC CHOSEN TO STUDY INVESTIGATIONAL BLOOD SUBSTITUTE IN TRAUMA PATIENTS

WHAT: COMMUNITY MEETING

Learn about a groundbreaking national clinical research study that may be conducted at St. Marys Hospital.

Andy Boggust, M.D., Consultant, Department of Emergency Medicine will present the details of the study, which will be conducted using an exception from informed consent requirements. HE will also be available for interviews at the conclusion of the presentation.

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PolyHeme® is a universally compatible, immediately available, oxygen-carrying resuscitative fluid designed to treat hemorrhagic shock where blood transfusion is required but blood is not available.

HOSPITAL BOILERPLATE

SAMPLE NOTICE FOR HOUSE OF WORSHIP BULLETIN

Rochester and Olmstead County may be one of a number of communities in the U.S. in which a clinical trial evaluating an investigational product, PolyHeme®, an oxygen-carrying blood substitute, in increasing survival in severely injured and bleeding persons who are in shock will be conducted. Treatment would begin before arrival at the hospital, either at the scene of the injury or in the ambulance, and continue through a 12 hour post injury period in the hospital. Persons eligible for this trial are expected to be unable to provide consent to participate because of the nature and extent of their injuries and will be enrolled under special federal regulations providing for emergency research. For more information, please contact:

Andy Boggust, M.D.
200 First St. SW
Rochester, Mn 55902

~~(507) 284-2511~~

Email address

Distribute to local houses of worship and request inclusion in their service bulletin.

PolyHeme®
Trauma Trial

Community Consultation

Saint Marys Hospital
www.mayoclinic.org/saintmaryshospital
Rochester, Minnesota

3 October 2003

Clinical Investigator

Andy Boggust, M.D.
Department of Emergency Medicine
Mayo Clinic
200 First St. SW
Rochester, Minnesota 55905
Tel.: (507) 284-2511
Email:

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*

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

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

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

What is the Standard of Care?

Represents the current treatment

In the prehospital

The patient receives
salt water
(blood is not available)

In the Hospital

The patient receives
salt water
and donated blood

Standard of Care Limitations

In the prehospital

- 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)

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

What is PolyHeme®?

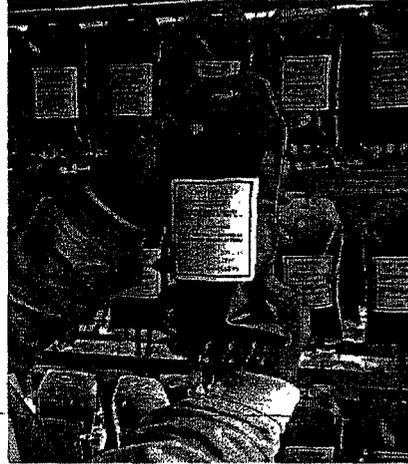
*A blood substitute
that carries oxygen*

1 unit of PolyHeme
=
1 unit of blood



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)



Why Use PolyHeme®?

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

Why Use PolyHeme®?

*To improve survival
of severely injured and bleeding
patients*

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*

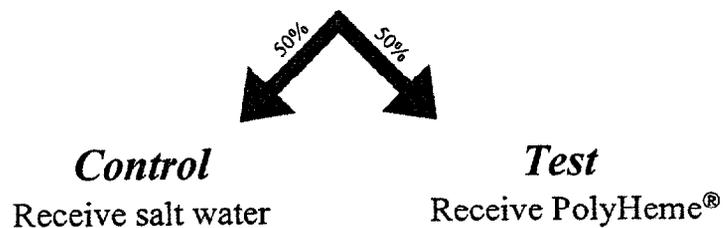
PolyHeme® Experience

Past studies have shown that PolyHeme

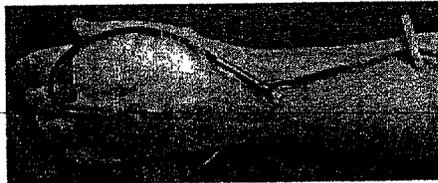
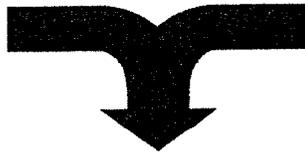
- Carries as much oxygen as blood
(1 unit of PolyHeme = 1 unit of blood)
- Reduces need for donated blood
- Has not caused organ damage
- Has replaced up to two times a person's entire blood volume (2 x 10 units = 20 units)

Trial Design: Before the Hospital

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



Prehospital Infusion



Trial Design: At the Hospital

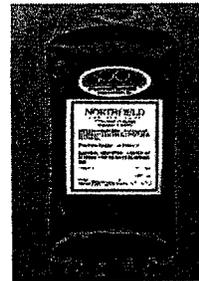
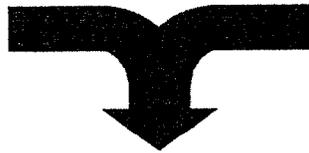
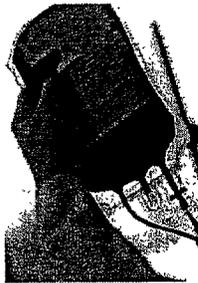
Control

- Salt water for hydration
- Donated blood to boost oxygen levels

Test

- Salt water for hydration
- PolyHeme® to boost oxygen levels
- Maximum dose of 6 units during first 12 hours
- Donated blood will be used thereafter

Hospital Infusion



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)

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

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

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

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

What is Exception from Informed Consent?

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

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

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

Consent Safeguards

- In some studies, the patient or a legally authorized representative (LAR) can give consent or object before the patient is enrolled in the study. Not possible in this study.
- Since consent cannot be obtained before enrollment, frequent attempts will be made to contact the patient's LAR and family to describe the study if the patient is incapacitated

Consent Safeguards

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

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)

Potential Risks of PolyHeme®

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

Patient Protection

The Mayo Clinic (Rochester) Institutional Review Board (IRB) is a group of medical, scientific, and nonscientific members of the community

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

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

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

Why is this research study being conducted?

This research study is being done to evaluate the life-saving potential of PolyHeme® when given to severely injured patients and bleeding patients, starting at the scene of injury.

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. It has an extended shelf life of over 12 months.

What is hemorrhagic shock?

Patients in the treatment group will receive salt water for hydration and PolyHeme® to boost oxygen levels. The maximum dose of PolyHeme will be 6 units during first 12 hours with blood being used thereafter.

Hemorrhagic means the patient has experienced massive blood loss. Shock is a life-threatening condition that might include:

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

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

Is PolyHeme® safe?

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

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

What can I expect from this research study?

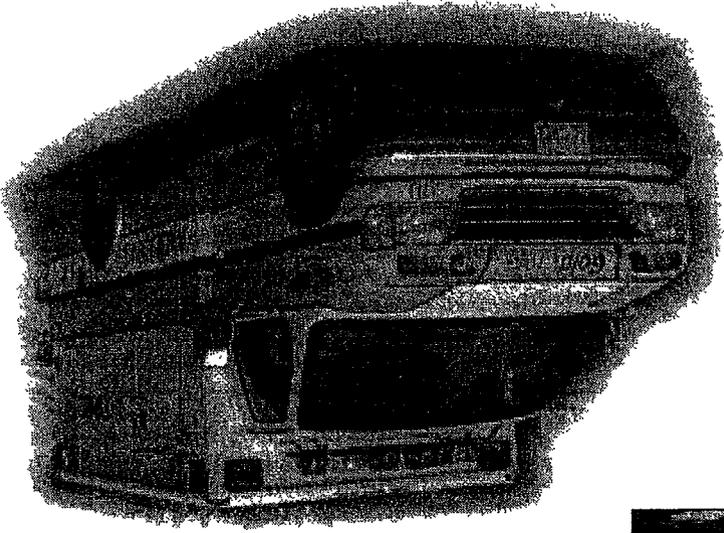
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Why is there a need for improvement in the way trauma patients are treated now?

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?

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



ID	Task Name	Start	Finish	3	Jan 4 '04	Jan 11 '04	Jan 18 '04	Jan 25 '04	Feb 1 '04	Feb 8 '04	Feb 15 '04	Feb 22 '04
				T	F	S	M	T	W	T	F	S
1	Internal Notification	Fri 1/2/04	Thu 2/5/04									
2	Opening Press Conference	Fri 1/2/04	Fri 1/2/04									
3	Clinical Trials Web page goes up	Fri 1/2/04	Thu 2/5/04									
4	Meet with the Department of Anesthesiology	Mon 1/5/04	Mon 1/5/04									
5	Meet with the Department of Surgery	Mon 1/5/04	Mon 1/5/04									
6	Meet with Department of Emergency Medicine	Wed 1/14/04	Wed 1/14/04									
7	Meet with the Department of Nursing	Wed 1/14/04	Wed 1/14/04									
8	Mayo Medical Transport Training	Thu 1/8/04	Thu 2/5/04									
9	Meet with Jehovah's Witness Community	Tue 1/20/04	Tue 1/20/04									
10	Meet with IMAA	Mon 1/12/04	Mon 1/12/04									
11	Meet with Diversity Council	Thu 1/22/04	Thu 1/22/04									
12	Meet with RMC Office of Diversity	Fri 1/16/04	Fri 1/16/04									
13	Media Notification	Mon 1/5/04	Tue 2/17/04									
14	Issue News release to regional media	Mon 1/5/04	Tue 1/6/04									
15	Availability for Regional Media Interviews	Wed 1/7/04	Tue 2/17/04									
16	Distribute House of worship bulletins	Mon 1/5/04	Mon 1/5/04									
17												
18												
19	Community Meetings	Mon 2/2/04	Mon 2/23/04									
20	Rochester Meeting #1	Mon 2/2/04	Mon 2/2/04									
21	Rochester Meeting #2	Mon 2/9/04	Mon 2/9/04									
22	Rochester Meeting #3	Mon 2/16/04	Mon 2/16/04									
23	Rochester Meeting #4	Mon 2/23/04	Mon 2/23/04									
24	Albert Lea Meeting	Wed 2/4/04	Wed 2/4/04									
25	Austin Meeting	Wed 2/11/04	Wed 2/11/04									
26	Owatonna Meeting	Wed 2/18/04	Wed 2/18/04									
27	Plainview Meeting	Fri 2/6/04	Fri 2/6/04									
28	Eyota Meeting	Fri 2/13/04	Fri 2/13/04									

Project: Community Notification.mpp Date: Wed 11/26/03	Task		Milestone		External Tasks	
	Split		Summary		External Milestone	
	Progress		Project Summary		Deadline	

ID	Task Name	Start	Finish
2	Opening Press Conference	Fri 1/2/04	Fri 1/2/04
3	Clinical Trials Web page goes up	Fri 1/2/04	Thu 2/5/04
4	Meet with the Department of Anesthesiology	Mon 1/5/04	Mon 1/5/04
5	Meet with the Department of Surgery	Mon 1/5/04	Mon 1/5/04
14	Issue News release to regional media	Mon 1/5/04	Tue 1/6/04
16	Distribute House of worship bulletins	Mon 1/5/04	Mon 1/5/04

Notes

WORSHIP BULLETIN

COMMUNITY NAME may be one of a number of communities in the U.S. in which a clinical trial evaluating an investigational product, PolyHeme®, an oxygen-carrying blood substitute, in increasing survival in severely injured and bleeding persons who are in shock will be conducted. Treatment would begin before arrival at the hospital, either at the scene of the injury or in the ambulance, and continue through a 12 hour post injury period in the hospital. Persons eligible for this trial are expected to be unable to provide consent to participate because of the nature and extent of their injuries and will be enrolled under special federal regulations providing for emergency research. For more information, please contact

Andy Boggust, M.D.
Department of Emergency Medicine
Mayo Clinic
200 First St SW
Rochester, MN 55902
(507) 284-7561

Polyheme.trial@mayo.edu
Mayo Clinic Clinical Trails

<http://mayoresearch.mayo.edu/mayo/research/trials/index.cfm>

15	Availability for Regional Media Interviews	Wed 1/7/04	Tue 2/17/04
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Notes

1.1.1. Local Print Media

Print media has long been considered a legal and appropriate means by which the public may be notified. The following publications were chosen based on either their wide or appropriately targeted distribution and / or

ID	Task Name	Start	Finish
<u>"Avallability for Regional Media Interviews" continued</u>			
	<u>Notes</u>		
	diversity of political and social readership. Print media to be targeted will include, but may not be limited to:		
	<ul style="list-style-type: none">• Albert Lea Tribune• Austin Daily Herald• Faribault County Register• Byron Review• Cannon Falls Beacon• Caledonia - The Argus• Chatfield News• Dodge Center Star Record• Faribault Daily News• Fairmont Sentinel• Fillmore County Journal• Goodhue News-Record• Harmony River Valley Reader• Hastings Star Gazette• Hayfield Herald• Kenyon Leader• Lake City Graphic• Lanesboro Republican-Leader• Le Center Leader• Le Roy Independent• Lewiston Journal• Litchfield Independent Review• New Richland Star• Northfield News• Owatonna People's Press• Pine Island News-Record• Preston Republican-Leader• Red Wing Republican Eagle		

ID	Task Name	Start	Finish
"Availability for Regional Media Interviews" continued			
	<u>Notes</u>		
	<ul style="list-style-type: none">• Rushford Tri-County Record• St. Charles Press• Stewartville Star• Wabasha County Herald• Wanamingo News-Record• West Concord Enterprise• Zumbrota News-Record		
	1.1.2. Broadcast Media -		
	Local media will be used to reach the public by via conventional news coverage and interviews with Principal Investigator. Television and radio stations to be targeted will include, but may not be limited to:		
	1.1.2.1. Radio		
	<ul style="list-style-type: none">○ Albert Lea: KATE (1450 AM)○ Austin: KAUS (1480 AM)○ Austin: KAUS (99.9 FM)○ Austin: KMSK (91.3 FM)○ Northfield: WCAL (89.3 FM)○ Northfield: KYMN (1080 AM)○ Rochester: KOLM (1520 AM)○ Rochester: KRPR (89.9 FM)○ Rochester: KROC (1340 AM), KZSE (90.7 FM)○ Rochester: KLSE (91.7 FM), KMSE (88.7 FM)○ Rochester: KWWK (96.5 FM)○ Rochester: KROC (106.9 FM)○ Stewartville: KYBA (105.3 FM)○ Winona: KHME (101.1 FM)○ Winona: KQAL (89.5 FM)		
	1.1.2.2. Television		
	<ul style="list-style-type: none">○ Austin: KAAL (Ch. 6)○ Austin: KSMQ (Ch. 15)		

ID	Task Name	Start	Finish
"Availability for Regional Media Interviews" continued			
	<u>Notes</u> <ul style="list-style-type: none"> ○ Rochester: KXLT (Ch. 47) ○ Rochester: KTTC (Ch. 10) ○ Minneapolis stations: KARE-TV ○ Minneapolis stations: WCCO-TV ○ ? Mason City 		
8	Mayo Medical Transport Training	Thu 1/8/04	Thu 2/5/04
10	Meet with IMAA	Mon 1/12/04	Mon 1/12/04
6	Meet with Department of Emergency Medicine	Wed 1/14/04	Wed 1/14/04
7	Meet with the Department of Nursing	Wed 1/14/04	Wed 1/14/04
12	Meet with RMC Office of Diversity	Fri 1/16/04	Fri 1/16/04
9	Meet with Jehovah's Witness Community	Tue 1/20/04	Tue 1/20/04
11	Meet with Diversity Council	Thu 1/22/04	Thu 1/22/04
20	Rochester Meeting #1 <u>Notes</u> Meeting Place: John Marshall High School, Library Meeting Time: 7pm	Mon 2/2/04	Mon 2/2/04
24	Albert Lea Meeting <u>Notes</u> Meeting Place: Albery Lee High School, Library Meeting Time: 7pm	Wed 2/4/04	Wed 2/4/04
27	Plainview Meeting <u>Notes</u> Meeting Place: Plainview High School, Library Meeting Time: 7pm	Fri 2/6/04	Fri 2/6/04
21	Rochester Meeting #2 <u>Notes</u> Meeting Place: Mayo High School, Library Meeting Time: 7pm	Mon 2/9/04	Mon 2/9/04
25	Austin Meeting <u>Notes</u> Meeting Place: Austin High School, Library Meeting Time: 7pm	Wed 2/11/04	Wed 2/11/04

ID	Task Name	Start	Finish
28	Eyota Meeting <u>Notes</u> Meeting Place: Dover-Eyota High School, Library Meeting Time: 7pm	Fri 2/13/04	Fri 2/13/04
22	Rochester Meeting #3 <u>Notes</u> Meeting Place: Century High School, Library Meeting Time: 7pm	Mon 2/16/04	Mon 2/16/04
26	Owatonna Meeting <u>Notes</u> Meeting Place: Owatonna Senior High School, Library Meeting Time: 7pm	Wed 2/18/04	Wed 2/18/04
23	Rochester Meeting #4 <u>Notes</u> Meeting Place: Bamber Valley Elementary School, Library Meeting Time: 7pm	Mon 2/23/04	Mon 2/23/04

Anderson, Tracey L. (IRB)

From: Boggust, Andy J., M.D.
Sent: Tuesday, June 15, 2004 1:12 PM
To: Anderson, Tracey L. (IRB)
Subject: one more thing

Hi Tracey,

One of the questions in the last minute item had to do with the Gold Cross service area. The attached file shows that portion of Olmsted county for which GC is responsible.

PSA: Olmsted County

