

**Denver Health Medical Center**  
**Denver, CO**



# NEWS

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## **Denver Health Medical Center begins research study of investigational blood substitute in trauma patients**

**--Treatment to Begin at Scene of Injury--**

### **FOR IMMEDIATE RELEASE**

Denver, Colorado – December 23, 2003

Denver Health Medical Center announced today that it is beginning patient enrollment in a national clinical trial to evaluate the safety and efficacy of PolyHeme<sup>®</sup>, an oxygen-carrying blood substitute, in treating severely injured and bleeding patients. In this controlled clinical study, adult patients meeting the eligibility criteria will be randomly assigned to initially receive infusions of either PolyHeme<sup>®</sup> or the current standard treatment, a saline solution. Treatment will begin before arrival at the hospital, either at the scene of the injury or in the ambulance, and continue during a 12-hour post injury period in the hospital.

In this trial it may not be possible to obtain informed consent from the patient or a legally authorized representative due to the urgency of the situation and the extent of the injuries. The study is therefore being conducted under a federal regulation that allows research to be conducted in certain emergent, life-threatening situations using an exception from the requirement for informed consent.

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Denver Health Medical Center, under the direction of Colorado Multiple Institutional Review Board (COMIRB), recently completed a process of community notification and consultation in connection with this study, as is mandated by this federal regulation. COMIRB 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. Based on its comprehensive review of the study protocol, the results of previous studies of the blood substitute, and the response of the community to participation in the study COMIRB has given approval for the study to be conducted at Denver Health. Emergency Medical Services personnel and hospital staff have also completed the necessary training.

“We are pleased that patient enrollment in this ambulance trial with a blood substitute may now begin,” said Ernest E. “Gene” Moore, M.D., Chief of Surgery and Trauma Services, Denver Health’s principal investigator. “This study could potentially lead to a change in the initial treatment of critically injured and bleeding patients that may result in improved survival.”

Persons wishing to decline participation in this study for religious or other reasons may contact the study coordinator, Jeffrey Long, 303-436-7906, to obtain a wristband expressing this choice. Specific risks and benefits of study participation may also be reviewed with the study coordinator or principal investigator, or for additional information please visit our website at:

<http://www.denverhealth.org/TraumaCenter/Polyheme.aspx>

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Denver Health, formerly known as Denver General Hospital, is the Rocky Mountain Region's only Level 1 academic trauma center, and the safety net hospital for the Denver area. The Denver Health system, which integrates acute and emergency care with public and community health, includes Denver Public Health, Rocky Mountain Poison and Drug Center, the Rocky Mountain Regional Trauma Center, Denver's 911 emergency medical response system, Denver Health Paramedic Division, 9 family health centers, 10 school-based health clinics, NurseLine, Correctional Care, Denver CARES, Denver Health Foundation and the Rocky Mountain Center for Medical Response to Terrorism, Mass Casualties and Epidemics.