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Bothell, WA 98021
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January 6, 2000

FOOD AND DRUG ADMINISTRATION
Dockets Management Branch HFA-305
12420 Parklawn Dr., Room 1-23
Rockville, MD 20857
Attn: Docket Number 95S-0158

Subject: BB IND-7371
Disclosure of Study Results, and Additional Community Consultation
Documentation, Protocol AHS02.

To Dockets Management Branch:

Reference is made to our Investigational New Drug Application for Humanized Monoclonal Antibody Hu23F2G for Hemorrhagic Shock, BB-IND 7371, which was originally submitted to the FDA Office of Therapeutics Research and Review on October 28, 1997. We also refer to:

- i) Protocol AHS02, entitled "Phase 2B Safety and Efficacy Study of Hu23F2G in Subjects with Hemorrhagic Shock" which was included in the original submission.
- ii) The guidelines described in 21 CFR §312.54(a) which require that Institutional Review Board (IRB) information concerning public disclosure be submitted to Docket 95S-0158, for clinical investigations involving an exemption from informed consent under 21 CFR§50.24.

The purpose of this submission is to provide documentation (21 CFR§50.24(a)(7)(iii)) concerning public disclosure following completion of Protocol AHS02. Individual sites IRBs have approved the ads included in this submission to apprise the communities, and researchers of the completed study. Each ad includes demographic characteristics of the research population, and the study results.

Listed below are eight of the IRBs which governed sites that conducted Protocol AHS02. Copies of actual advertisements for disclosure of study results as approved by these IRBs are included in this submission.

Committee on Investigations Involving Human Subjects

University of California - San Diego
La Jolla, CA

Human Subjects Review Committee

University of Washington
Seattle, WA

95S-0158

SUP21

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UT Memphis Institutional Review Board

University of Tennessee - Memphis
Memphis, TN

Human Subjects Research Committee

Hennepin County Medical Center
Minneapolis, MN

Metro Health Medical Center – Institutional Review Board

Metro Health Medical Center
Cleveland, OH

The Colorado Multiple Institutional Review Board

Denver Health Medical Center
Denver, CO

Vanderbilt University Institutional Review Board (Additional information regarding community consultation for this site is included in this submission.)

Vanderbilt University
Nashville, TN

University of Missouri – Kansas City Adult Health Sciences Institutional Review Board
(Additional information regarding community consultation for this site is included in this submission.)

Truman Medical Center
Kansas City, MO

If you have any comments or questions regarding this submission, please do not hesitate to contact me at (425) 415-2297.

Sincerely,



Jeff Hesselberg, M.B.A.
Associate Director, Regulatory Affairs

UCSD MEDICAL CENTER

San Diego, California

Division of Trauma

TRAUMA STUDY RESULTS

University of California, San Diego Medical Center recently participated in a research study to evaluate an investigational drug that may help severely injured patients. The investigational drug being tested is called Hu23F2G (LuekArrest™). The research study is sponsored by ICOS Corporation (Bothell, Washington). Hu23F2G acts on the white blood cells and may prevent them from causing damage to the body's major organs following trauma. In order to determine the safety and effectiveness of this new drug, research studied 150 trauma victims at 11 trauma centers throughout the United States. In the clinical trial, some patients received Hu23F2G along with standard care and some patients received the standard care for severe injury alone.

Patients were enrolled into the study in one of three ways. First, patients gave their own informed consent if they were able. Second, if a patient were unable to give consent, then upon arrival in the emergency department the hospital staff attempted to reach a family member. If this was successful, the family was asked to provide informed assent. Third, if a family member was not located within three hours, the patient was enrolled under the Food and Drug Administration (FDA) regulations waiving the requirement to obtain an informed consent. The effort to locate and inform family continued after the patient had been enrolled into the study under the FDA regulations waiving the requirement to obtain an informed consent. Use of the FDA regulations waiving the requirement to obtain an informed consent in this study was approved by the FDA and the Committee on Investigations Involving Human Subjects, which is charged with ethical oversight of patient research at University of California, San Diego Medical Center.

Enrollment into this study was completed on January 26, 1999. Across the entire study, 14% of patients signed their own consent, 53% had a family member provide informed assent and 33% were enrolled with waiver if informed consent. At University of California, San Diego Medical Center, 14 patients were enrolled into the study from 4/20/98 to 1/26/99. 1 patient signed their own consent, 10 had a family member provide informed assent and 3 patients were enrolled with a waiver of informed consent.

In this study, the average patient age was 36 year old, males were enrolled about twice as often as females. The majority of the patients were Caucasian (58%), followed by African American (25%) and other races (17%). At the University of California, San Diego Medical Center the average patient age was 32 years old, 9 males and 5 females were enrolled. The majority of the patient were other races (50%), followed by Caucasian (43%) and African American (7%).

Preliminary analysis of the study has been performed. Hu23F2G appeared to be safe in the patient population. A total of 11 patients (7%) died in the study. The death rate was 10% in patients who received standard of care alone and 6% in patients who received Hu23F2G. Although the endpoints that the study was designed to measure were no different between the patients that received standard of care and patients that received Hu23F2G along with standard of care, there was a suggestion that those patients who received the higher dose of Hu23F2G had decreased heart and lung failure compared with those patient who received standard care only. Further analyses of the data are underway.

Any questions about this study should be directed to David B. Hoyt, MD at (619) 294-6400.

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Division of Trauma

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In this study, the average patient age was 36 year old, males were enrolled about twice as often as females. The majority of the patients were Caucasian (53%), followed by African American (25%) and other races (17%). At the University of California, San Diego Medical Center the average patient age was 32 years old, 9 males and 3 females were enrolled. The majority of the patient were other races (50%), followed by Caucasian (43%) and African American (7%).

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Any questions about this study should be directed to David B. Hoyt, MD at (619) 294-6488.

Alpha 2 Omega Presents "Rivers of Life"



On Saturday, November 6, 1999, Alpha 2 Omega Training & Retail Center presents its First Annual Black Tie Benefit "Rivers of Life." This benefit will be held at the Holiday Inn on the Bay, 1355 N. Harbor Drive from 6 p.m. to 10 p.m. The Pindiana Spirit Awards will be presented to some of San Diego Community Leaders and Entrepreneurs who are dedicated and committed to the social and economical development and advancement of our community. All guests at this benefit will enjoy a fabulous fashion show, buffet, silent auction, DJ services by Preacherman Production, live entertainment by Sir Kippy Marks an improv-o-linist, Bennie Herron Poet extraordinary, dance production by Foster-King Dance Collection, and a special CD Debut by Norma Handy and much more.

Clothes donated by Graf Furs, Tux of Class, Wilsons Leather, Samira, Elite, Rivers

International, Georgiou, La Carlen Apparels, Ekaabo, Designer Studio, Jajasha International, Cultures by Najam, International Male, The Red Zone, and Fashion Careers College Top Designers.

General Admission is \$50.00 and VIP \$100.00. Tickets can be purchased at "It is Written Bookstore" in Lemon Grove, Elite Fashions-Downtown San Diego, and Angelas Salon in Vista. All funds raised will benefit Alpha 2 Omega Training and Retail Center.

Our mission statement is to provide quality education and training to unemployed and underemployed individuals in customer service, retail and life management, challenging them to become socially and economically self-sufficient.

For more information about the Event of the Year and how you can participate and support a new training program call 619.842.5125

UCSD Medical Center Trauma Study Results

University of California, San Diego Medical Center recently participated in a research study to evaluate an investigational drug that may help severely injured patients. The investigational drug being tested is called Hu23F2G (LuekArrest™). The research study is sponsored by ICOS Corporation (Bothell, Washington). Hu23F2G acts on the white blood cells and may prevent them from causing damage to the body's major organs following trauma. In order to determine the safety and effectiveness of this new drug, research studied 150 trauma victims at 11 trauma centers throughout the United States. In the clinical trial, some patients received Hu23F2G along with standard care and some patients received the standard care for severe injury alone.

Patients were enrolled into the study in one of three ways. First, patients gave their own informed consent if they were able. Second, if a patient were unable to give consent, then upon arrival in the emergency department the hospital staff attempted to reach a family member. If this was successful, the family was asked to provide informed assent. Third, if a family member was not located within three hours, the patient was enrolled under

the Food and Drug Administration (FDA) regulations waiving the requirement to obtain an informed consent. The effort to locate and inform family continued after the patient had been enrolled into the study under the FDA regulations waiving the requirement to obtain an informed consent. Use of the FDA regulations waiving the requirement to obtain an informed consent in this study was approved by the FDA and the Committee Investigations Involving Human Subjects, which is charged with ethical oversight of patient research at University of California, San Diego Medical Center.

Enrollment into this study was completed on January 26, 1999. Across the entire study, 14% of patients signed their own consent, 53% had a family member provide informed assent and 33% were enrolled with waiver if informed consent. At University of California, San Diego Medical Center, 14 patients were enrolled into the study from 4/20/98 to 1/26/99. 1 patient signed their own consent, 10 had a family member provide informed assent and 3 patients were enrolled with a waiver of informed consent.

In this study, the average patient age was 36 year old, males were enrolled about

twice as often as females. The majority of the patients were Caucasian (53%), followed by African American (25) and other races (17%). At the University of California, San Diego Medical Center the average patient age was 32 year old, 9 males and 5 females were enrolled. The majority of the patients were other races (50%), followed by Caucasian (43) and African American (7%).

Preliminary analysis of the study has been performed. Hu23F2G appeared to be safe in the patient population. A total of 11 patients (7%) died in the study. The death rate was 10% in patients who received standard care alone and 6% in patients who received Hu23F2G. Although the endpoints that the study was designed to measure were no different between the patients that received standard care and patients that received Hu23F2G along with standard care, there was a suggestion that those patients who received the higher dose of Hu23F2G had decreased heart and lung failure compared with those patients who received standard care only. Further analyses of the data are underway.

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Advertisement ran in the Seattle Post Intelligencer on December 23, 1999.

PAID ADVERTISEMENT

Trauma Study Results

Harborview Medical Center recently participated in a research study to evaluate an investigational drug that may help severely injured patients. The investigational drug being tested is called Hu23F2G (LeukArrestSM) and is available only in research studies. The research study is sponsored by ICOS Corporation (Bothell, Washington). Hu23F2G acts on the white blood cells and may prevent them from causing damage to the body's major organs following trauma. In order to determine the safety and effectiveness of this new drug, researchers studied 150 trauma victims at 11 trauma centers throughout the United States. All patients in the study received standard emergency care for severe injury and some patients received Hu23F2G.

Patients were enrolled into the study in one of three ways. Patients gave their own informed consent if they were able. If a patient was unable to give consent, upon arrival in the emergency department, the hospital staff attempted to reach a family member. If this was successful, the family was asked to provide informed consent. If a family member was not located within three hours, the patient was enrolled under the Food and Drug Administration (FDA) regulations waiving the requirement to obtain an informed consent. The effort to locate and inform family continued after the patient had been enrolled in the study. Use of the FDA regulations waiving the requirement to obtain an informed consent in this study was approved by the FDA and the Human Subjects Review Committee, University of Washington, which is charged with ethical oversight of patient research at Harborview Medical Center.

Enrollment of all 150 trauma patients was completed on January 26, 1999. At Harborview Medical Center, 32 patients were enrolled into the study from 2/3/98 to 1/1/99. No patients signed their own consent, 16 had a family member provide informed consent and 16 patients were enrolled with a waiver of informed consent.

In this study, the average patient age was 36 years old; males were enrolled about twice as often as females. The majority of the patients were Caucasian (58%), followed by African American (23%) and other races (17%). At Harborview Medical Center the average patient age was 35 years old, 22 males and 10 females were enrolled. The majority of the patients enrolled were Caucasian (72%), followed by African American (16%) and other races (15%).

Preliminary analysis of the study has been performed. Hu23F2G appeared to be safe in this patient population. A total of 11 patients (7%) died in the study. The death rate was 10% in the patients who received standard care alone and 6% in patients who received Hu23F2G in addition to standard care. The outcomes measured in the study concluded no difference between patients who received standard care and those who received Hu23F2G with standard care. However, closer examination of the data revealed that the patients who received the higher dose of Hu23F2G had decreased heart and lung failure compared with those patients who received the lower dose of Hu23F2G or standard care only. Further analyses of the data are underway.

Any questions about this study should be directed to Nicholas Veeder, MD at 206-731-3174.

Advertisement ran in the Seattle Times on December 23, 1999.

PAID ADVERTISEMENT

Trauma Study Results

Harborview Medical Center recently participated in a research study to evaluate an investigational drug that may help severely injured patients. The investigational drug being tested is called Hu23F2G (LeukArrestTM) and is available only in research studies. The research study is sponsored by ICOS Corporation (Bothell, Washington). Hu23F2G acts on the white blood cells and may prevent them from causing damage to the body's major organs following trauma. In order to determine the safety and effectiveness of this new drug, researchers studied 150 trauma victims at 11 trauma centers throughout the United States. All patients in the study received standard emergency care for severe injury and some patients received Hu23F2G.

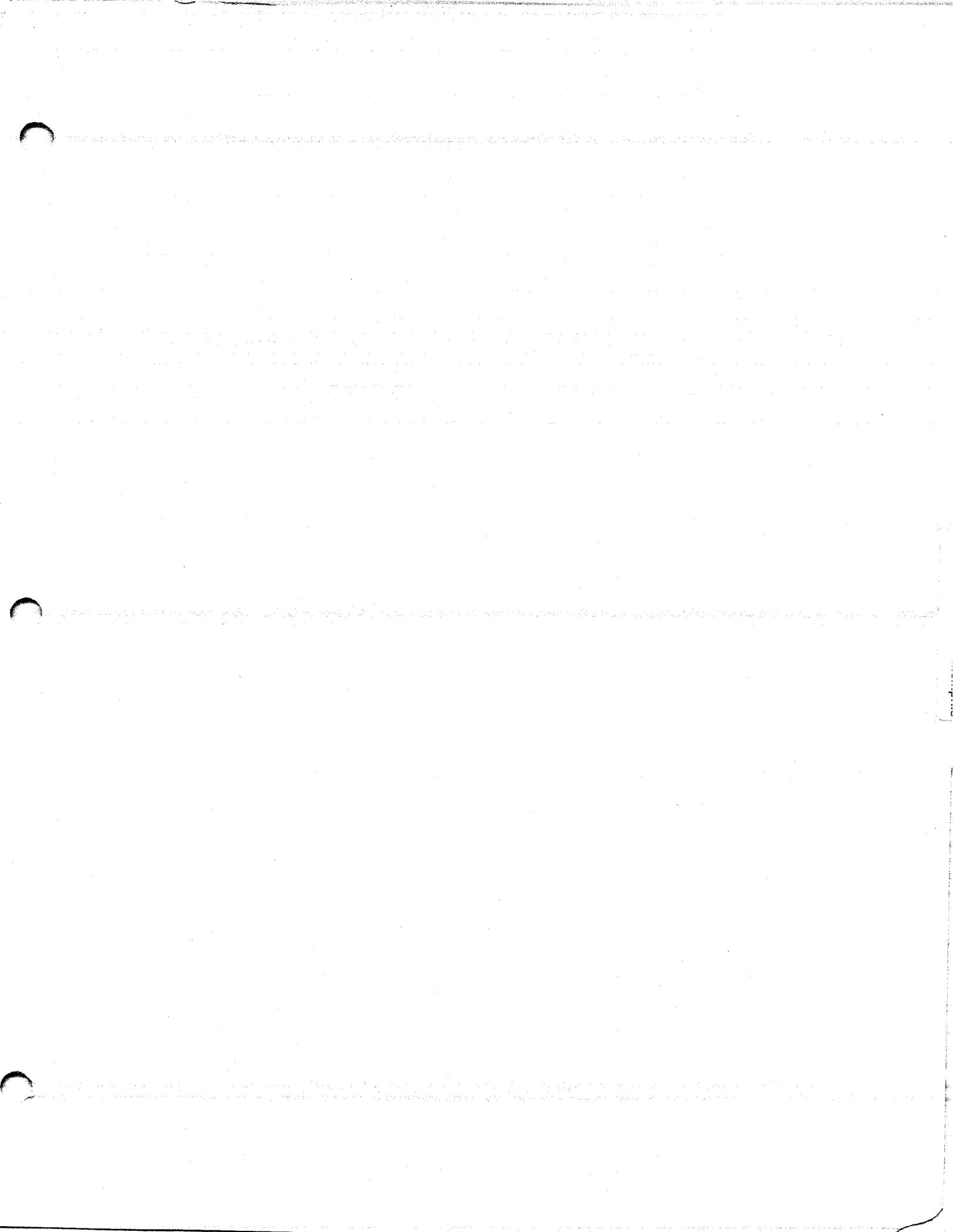
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Enrollment of all 150 trauma patients was completed on January 26, 1999. At Harborview Medical Center, 32 patients were enrolled into the study from 2/3/98 to 1/1/99. No patients signed their own consent, 16 had a family member provide informed consent and 16 patients were enrolled with a waiver of informed consent.

In this study, the average patient age was 36 years old; males were enrolled about twice as often as females. The majority of the patients were Caucasian (58%), followed by African American (25%) and other races (17%). At Harborview Medical Center the average patient age was 35 years old, 22 males and 10 females were enrolled. The majority of the patients enrolled were Caucasian (72%), followed by African American (16%) and other races (15%).

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Any questions about this study should be directed to Nicholas Vedder, MD at 206-731-3174.



Public Notice

ADVERTISEMENT TO BIDDERS

Bids will be received by the Shelby County Schools of Education for Emergency Asbestos Abatement for All Shelby County Schools, Shelby County, Tennessee.

The amount, location and type of work to be performed are not known at this time. It is possible that the work may include, but is not limited to, the abatement of the following items: TSI, pipe lagging and fitting insulation, fireproofing, spray applied acoustical ceiling, metal lath and plaster walls and ceiling, flooring materials, mastics, window glazing, sheet rock/mud/tape, window putty, ceiling tile, contaminated soil, roofing materials, cementitious asbestos materials, floor-tiles and mastic, cobweb and mastics.

Bids shall be enclosed in a sealed envelope and addressed to Mr. Richard Holden, Assistant Superintendent, Operations Division, Shelby County Schools, 7661 Winchester Road, Memphis, Tennessee, 38125; and marked "Bid for Emergency Asbestos Abatement For All Shelby County Schools." The name address and telephone and fax numbers of the Bidder, their license number and expiration date, insurance carrier, insured amount and insurance expiration date must also be placed on the outside of the envelope containing the bid.

Bids will be received until 2:00 p.m. on Monday, October 18, 1999, at the office of the Shelby County Schools Maintenance Department, 7661 Winchester Road, Memphis, Tennessee, 38125, and immediately thereafter all bids will be publicly opened and read aloud. The bid opening time shall be established by the time place of the Designer. There will be no notification of selection at the time of the bid opening. The Contractor is not required to attend this meeting. The Owner will notify all bidders of the outcome of selection by fax or telephone after the Owner has applied the unit costs to the mock project(s) and reviewed the Contractor's information as required in Section 00100, Instructions To Bidders. The selection process is anticipated to take no less than three (3) weeks.

All information relating to a bid shall be contained within the Bidder's sealed envelope, and the officer in charge of bidding shall not consider bidding information appearing outside the envelope containing said bid.

Contract documents may be examined at the following locations:

1. Pickering Environmental Consultants, Inc., 1750 Madison Avenue, Suite 500, Memphis, Tennessee, 38104
2. F.W. Dodge Plan Room, 5865 Ridgeway Center Parkway, Memphis, Tennessee, 38120.
3. Builder's Exchange Plan Room, 612 South Cooper, Memphis, Tennessee, 38104.
4. Memphis Area Minority Contractor's Association, 1190 Walker, Memphis, Tennessee, 38107.
5. Uniform Certification Agency, 4111 West Park Loop, Building 48, University of Memphis, South Campus, Memphis, Tennessee, 38111.

Complete sets of Contract Documents may be obtained for no charge at the office of the Designer after September 6, 1999.

Public Notice

Trauma Study Results

The University of Tennessee-Memphis recently participated in a research study to evaluate an investigational drug that may help severely injured patients. The study was conducted at The Regional Medical Center at Memphis' (The MED) Elvis Presley Memorial Trauma Center. The investigational drug being tested is called Hu23F2G (LeukArrest). The research study is sponsored by ICOS Corporation (Bothell, Washington). Hu23F2G acts on the white blood cells and may prevent them from causing damage to the body's major organs following trauma. In order to determine the safety and effectiveness of this new drug, researchers studied 150 trauma victims at 11 trauma centers throughout the United States, including The MED's Trauma Center. In the clinical trial, some patients received Hu23F2G along with standard care and some patients received the standard care for severe injury alone.

Patients were enrolled into the study in one of three ways. First, patients gave their own informed consent if they were able. Second, if a patient was unable to give consent, then upon arrival in the emergency department the hospital staff attempted to reach a family member. If this was successful, the family was asked to provide in-

formed assent. Third, if a family member was not located within three hours, the patient was enrolled under the Food and Drug Administration (FDA) regulations waiving the requirement to obtain an informed consent. The effort to locate and inform family continued after the patient had been enrolled into the study under the FDA regulations waiving the requirement to obtain an informed consent. Use of the FDA regulations waiving the requirement to obtain an informed consent in this study was approved by the FDA and the University of Tennessee-Memphis Institutional Review Board, which is charged with ethical oversight of patient research at University of Tennessee-Memphis.

Enrollment into this study was completed on January 26, 1999. Across the entire study, 14% of patients signed their own consent, 53% had a family member provide informed assent and 33% were enrolled with waiver of informed consent. At the University of Tennessee-Memphis, 26 patients were enrolled into the study from 6/18/98 to 1/24/99. Fourteen patients signed their own consent, 11 had a family member provide informed assent and 1 patient was enrolled with a waiver of informed consent.

In this study, the average

patient age was 36-years-old, males were enrolled about twice as often as females. The majority of the patients were Caucasian (58%), followed by African American (25%) and other races (17%). At University of Tennessee-Memphis the average patient age was 36 years old, 20 males and 6 females were enrolled. The majority of the patients were African-American (61%), followed by Caucasian (35%) and other races (4%).

Preliminary analysis of the study has been performed. Hu23F2G appeared to be safe in this patient population. A total of 11 patients (7%) died in the study. The death rate was 10% in patients who received standard of care alone and 6% in patients who received Hu23F2G. Although the points that the study was designed to measure were no different between the patients that received standard of care and the patients that received Hu23F2G along with standard of care, there was a suggestion that those patients who received the higher dose of Hu23F2G had decreased heart and lung failure compared with those patients who received standard care only. Further analyses of the data are underway.

Any questions about this study should be directed to Timothy Fabian, MD at 901-448-5914.

Trauma Study Results

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Patients were enrolled into the study in one of three ways. First, patients gave their own informed consent if they were able. Second, if a patient was unable to give consent, then upon arrival in the emergency department the hospital staff attempted to reach a family member. If this was successful, the family was asked to provide in-

formed assent. Third, if a family member was not located within three hours, the patient was enrolled under the Food and Drug Administration (FDA) regulations waiving the requirement to obtain an informed consent. The effort to locate and inform family continued after the patient had been enrolled into the study under the FDA regulations waiving the requirement to obtain an informed consent. Use of the FDA regulations waiving the requirement to obtain an informed consent in this study was approved by the FDA and the University of Tennessee-Memphis Institutional Review Board, which is charged with ethical oversight of patient research at University of Tennessee-Memphis.

Enrollment into this study was completed on January 26, 1999. Across the entire study, 14% of patients signed their own consent, 53% had a family member provide informed assent and 33% were enrolled with waiver of informed consent. At the University of Tennessee-Memphis, 26 patients were enrolled into the study from 6/18/98 to 1/24/99. Fourteen patients signed their own consent, 11 had a family member provide informed assent and 1 patient was enrolled with a waiver of informed consent.

In this study, the average

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Preliminary analysis of the study has been performed. Hu23F2G appeared to be safe in this patient population. A total of 11 patients (7%) died in the study. The death rate was 10% in patients who received standard of care alone and 6% in patients who received Hu23F2G. Although the points that the study was designed to measure were no different between the patients that received standard of care and the patients that received Hu23F2G along with standard of care, there was a suggestion that those patients who received the higher dose of Hu23F2G had decreased heart and lung failure compared with those patients who received standard care only. Further analyses of the data are underway.

Any questions about this study should be directed to Timothy Fabian, MD at 901-448-5914.

Public Notice

Public Notice

Public Notice

Public Notice

Advertisement ran in the Star Tribune on November 29, 1999.

Trauma Study Results

Hennepin County Medical Center recently participated in a research study to evaluate an investigational drug that may help severely injured patients. The investigational drug being tested is called Hu23F2G (LeukArrest™). The research study is sponsored by ICOS Corporation (Bothell, Washington). Hu23F2G acts on the white blood cells and may prevent them from causing damage to the body's major organs following trauma. In order to determine the safety and effectiveness of this new drug, researchers studied 150 trauma victims at 11 trauma centers throughout the United States. In the clinical trial, some patients received Hu23F2G along with standard care and some patients received the standard care for severe injury alone.

Patients were enrolled into the study in one of three ways. First, patients gave their own informed consent if they were able. Second, if a patient were unable to give consent, then upon arrival in the emergency department the hospital staff attempted to reach a family member. If this was successful, the family was asked to provide informed assent. Third, if a family member was not located within three hours, the patient was enrolled under the Food and Drug Administration (FDA) regulations waiving the requirement to obtain an informed consent. The effort to locate and inform family continued after the patient had been enrolled into the study under the FDA regulations waiving the requirement to obtain an informed consent. Use of the FDA regulations waiving the requirement to obtain an informed consent in this study was approved by the FDA and the Human Subjects Research Committee, which is charged with ethical oversight of patient research at Hennepin County Medical Center.

Enrollment into this study was completed on January 26, 1999. Across the entire study, 14% of patients signed their own consent, 53% had a family member provide informed assent and 33% were enrolled with waiver of informed consent. At Hennepin County Medical Center, 23 patients were enrolled into the study from 7/13/98 to 1/17/99. No patients signed their own consent, 12 had a family member provide informed assent, and 11 patients were enrolled with a waiver of informed consent.

In this study, the average patient age was 36 years old, males were enrolled about twice as often as females. The majority of the patients were Caucasian (58%), followed by African American (25%) and other races (17%). At Hennepin County Medical Center the average patient age was 40 years old, 15 males and 8 females were enrolled. The majority of the patients were Caucasian (57%), followed by African American (30%) and other races (13%).

Preliminary analysis of the study has been performed. Hu23F2G appeared to be safe in this patient population. A total of 11 patients (7%) died in the study. The death rate was 10% in patients who received standard of care alone and 6% in patients who received Hu23F2G. Although the endpoints that the study was designed to measure were no different between the patients that received standard of care and the patients that received Hu23F2G along with standard of care, there was a suggestion that those patients who received the higher dose of Hu23F2G had decreased heart and lung failure compared with those patients who received standard care only. Further analyses of the data are underway.

Any questions about this study should be directed to Michael A. West, MD at:
(612) 347-2810

Trauma Study Results Reported

MetroHealth Medical Center recently participated in a research study to evaluate an investigational drug that may help severely injured patients. The investigational drug being tested is called Hu23F2G (LeukArrest™). The research study is sponsored by ICOS Corporation, located in Bothell, Washington. Hu23F2G acts on the white blood cells and may prevent them from causing damage to the body's major organs following trauma. In order to determine the safety and effectiveness of this new drug, researchers studied 150 trauma victims at 11 trauma centers throughout the United States. In the clinical trial, some patients received Hu23F2G along with standard care and some patients received the standard care for severe injury alone.

Patients were enrolled into the study in one of three ways. First, patients gave their own informed consent if they were able. Second, if a patient was unable to give consent, then upon arrival in the emergency department the hospital staff attempted to reach a family member. If this was successful, the family was asked to provide informed assent. Third, if a family member was not located within three hours, the patient was enrolled under the Food and Drug Administration (FDA) regulations waiving the requirement to obtain an informed consent. The effort to locate and inform family continued after the patient had been enrolled into the study under the FDA regulations waiving the requirement to obtain an informed consent. Use of the FDA regulations waiving the requirement to obtain an informed consent in this study was approved by the FDA and the MetroHealth Medical Center IRB, which is charged with ethical oversight of patient research at MetroHealth Medical Center.

Enrollment into this study was completed on January 26, 1999. Across the entire study, 14 percent of patients signed their own consent, 53 percent had a family member provide informed assent and 33 percent were enrolled with waiver of informed consent. At MetroHealth Medical Center, 2 patients were enrolled into the study from October 15, 1998 to December 7, 1998. One patient signed his own consent, one patient had a family member provide informed assent, and no patients were enrolled with a waiver of informed consent.

In this study, the average patient age was 36 years old, and males were enrolled about twice as often as females. The majority of the patients were Caucasian (58 percent), followed by African American (25 percent) and other races (17 percent). At MetroHealth Medical Center, the average patient age was 60 years old, one male and one female were enrolled, and 100 percent (both) of the patients were Caucasian.

Preliminary analysis of the study has been performed. Hu23F2G appeared to be safe in this patient population. A total of 11 patients (7 percent) died in the study. The death rate was 10 percent in patients who received standard care alone and 6 percent in patients who received Hu23F2G. Although the endpoints that the study were designed to measure were no different between the patients that received standard care and the patients that received Hu23F2G along with standard care, there was a suggestion that those patients who received the higher dose of Hu23F2G had decreased heart and lung failure compared with those patients who received standard care only. Further analyses of the data are underway.

Any questions about this study should be directed to Mark Malangoni, M.D., clinical chairperson, Department of Surgery, at (216)778-8324.



MetroHealth Medical Center
2500 MetroHealth Drive
Cleveland, Ohio 44109-1998

Reporte del Resultados del Estudio de Trauma

Metro Health Medical Center recientemente participó en un estudio de investigación para evaluar una droga que estaba siendo investigada que puede ayudar a pacientes severamente heridos. La droga investigada que está siendo probada es llamada Hu23F2G (LeukArrestTM). El estudio de investigación está patrocinado por ICOS Corporation, localizada en Bothell, Washington. Hu23F2G actúa en las células blancas de la sangre y puede prevenir el que estas causen daño a los órganos mayores del cuerpo después de un trauma. En orden para determinar la seguridad y la efectividad de esta nueva droga, los estudiosos estudiaron a 150 víctimas en 11 centros de trauma a través de los Estados Unidos. En el proceso clínico, algunos pacientes recibieron Hu23F2G junto con el cuidado rutinario y algunos pacientes recibieron el cuidado rutinario para heridas severas solamente.

Los pacientes fueron enrolados en el estudio en una de tres formas. Primero, los pacientes dieron su consentimiento informando si estaban dispuestos. Segundo, si un paciente no estaba dispuesto a dar su consentimiento, entonces al arribar al departamento de emergencia el personal del hospital intentaría alcanzar a un miembro de la familia. Si esto fue posible, se le preguntó a la familia el proveer un consentimiento informado. Tercero, si un miembro de la familia no fue localizado dentro de tres horas, el paciente fue enrolado bajo las regulaciones de la -Food and Drug Administration- (FDA) levantando el requerimiento de obtener un consentimiento informado. El esfuerzo de localizar e informar a la familia continuó después de que el paciente fue enrolado en el estudio bajo las regulaciones de la FDA levantando el requerimiento de consentimiento. El uso de las regulaciones de la FDA para levantar el requerimiento para obtener un consentimiento informado en este estudio fue aprobado por la FDA y el MetroHealth Medical Center IRB, el cual está a cargo de sobre ver la ética de los estudios en los pacientes en el MetroHealth Medical Center.

El enrolamiento de este estudio fue completado el 26 de enero de 1999. A través de todo el estudio, 14 por ciento de los pacientes firmaron su propio consentimiento, 53 por ciento tuvieron a un miembro de la familia para proveer el consentimiento informado y 33 por ciento fueron enrolados con levantamientos de consentimientos informados. En MetroHealth Medical Center, 2 pacientes fueron enrolados en el estudio del 15 de octubre de 1998 a el 7 de diciembre de 1998. Un paciente firmó su propio consentimiento, un paciente tuvo a un miembro de la familia que proveyó el consentimiento informado, y ningún paciente fue enrolado con un levantamiento de consentimiento informado.

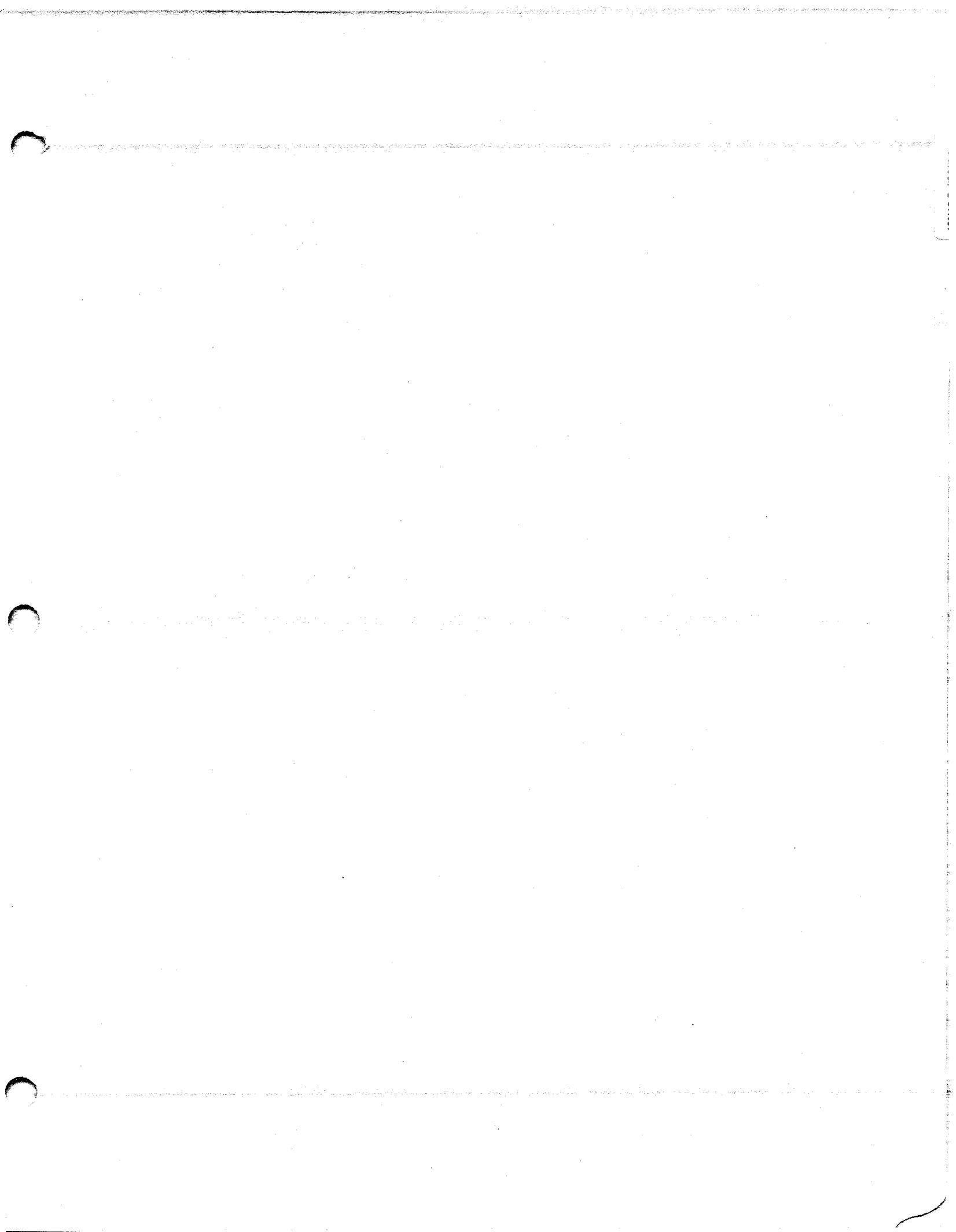
En este estudio, el paciente promedio fue de 36 años de edad, y los varones fueron enrolados como dos veces más que las mujeres. La mayoría de los pacientes fueron blancos (58 por ciento), seguidos por los Afro Americanos (25 por ciento) y otras razas (17 por ciento). En MetroHealth Medical Center, la edad promedio del paciente fue de 60 años, uno varón y uno mujer fueron enrolados, y ambos pacientes eran blancos.

El análisis preliminar del estudio ha sido hecho. Hu23F2G aparece como seguro en esta población de pacientes. Un total de 11 pacientes (7 por ciento) murieron en el estudio. La tasa de muerte fue de un 10 por ciento en pacientes que solo recibieron el cuidado rutinario y de 6 por ciento en pacientes que recibieron Hu23F2G. Aunque los puntos finales para los que el estudio fue diseñado a medir no fueron diferentes entre los pacientes que recibieron cuidado rutinario y los pacientes que recibieron Hu23F2G junto con los cuidados rutinarios, hubo una sugerencia de que esos pacientes que recibieron Hu23F2G habían disminuido fallas del corazón y los pulmones comparados con aquellos pacientes que recibieron cuidado rutinario solamente. Análisis futuros de la data están de camino.

Cualquier pregunta acerca de este estudio puede ser dirigida a Mark Malangoni, M.D., presidente clínico, Departamento de Cirugía, al (216) 778-8324.



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Advertisement ran in the Rocky Mountain News on Tuesday, November 9, 1999.

Trauma Study Results

Denver Health Medical Center recently participated in a research study to evaluate an investigational drug that may help severely injured patients. The investigational drug being tested is called Hu23F2G (LeukArrest™). The research study is sponsored by ICOS Corporation (Bothell, Washington). Hu23F2G acts on the white blood cells and may prevent them from causing damage to the body's major organs following trauma. In order to determine the safety and effectiveness of this new drug, researchers studied 150 trauma victims at 11 trauma centers throughout the United States. In the clinical trial, some patients received Hu23F2G along with standard care and some patients received the standard care for severe injury alone.

Patients were enrolled into the study in one of three ways. First, patients gave their own informed consent if they were able. Second, if a patient were unable to give consent, then upon arrival in the emergency department the hospital staff attempted to reach a family member. If this was successful, the family was asked to provide informed assent. Third, if a family member was not located within three hours, the patient was enrolled under the Food and Drug Administration (FDA) regulations waiving the requirement to obtain an informed consent. The effort to locate and inform family continued after the patient had been enrolled into the study under the FDA regulations waiving the requirement to obtain an informed consent. Use of the FDA regulations waiving the requirement to obtain an informed consent in this study was approved by the FDA and the Colorado Multiple IRB, which is charged with ethical oversight of patient research at Denver Health Medical Center.

Enrollment into this study was complete on January 25, 1999. Across the entire study, 14% of patients signed their own consent, 53% had a family member provide informed assent and 33% were enrolled with waiver of informed consent. At Denver Health Medical Center, 4 patients were enrolled into the study from 10/21/98 to 12/14/98. No patients signed their own consent, 4 had a family member provide informed assent, and no patients were enrolled with a waiver of informed consent.

In this study, the average patient age was 35 years old, males were enrolled about twice as often as females. The majority of the patients were Caucasian (58%), followed by African American (25%) and other races (17%). At Denver Health Medical Center the average patient age was 24 years old, 3 males and 1 female were enrolled. The majority of the patients were Caucasian (75%), followed by other races (25%).

Preliminary analysis of the study has been performed. Hu23F2G appeared to be safe in this patient population. A total of 11 patients (7%) died in the study. The death rate was 10% in patients who received standard of care alone and 6% in patients who received Hu23F2G. Although the endpoints that the study was designed to measure were no different between the patients that received standard of care and the patients that received Hu23F2G along with standard of care, there was a suggestion that those patients who received the higher dose of Hu23F2G had decreased heart and lung failure compared with those patients who received standard care only. Further analyses of the data are underway.

Any questions about this study should be directed to Ernest E. Moore, MD at (303) 436-6558.

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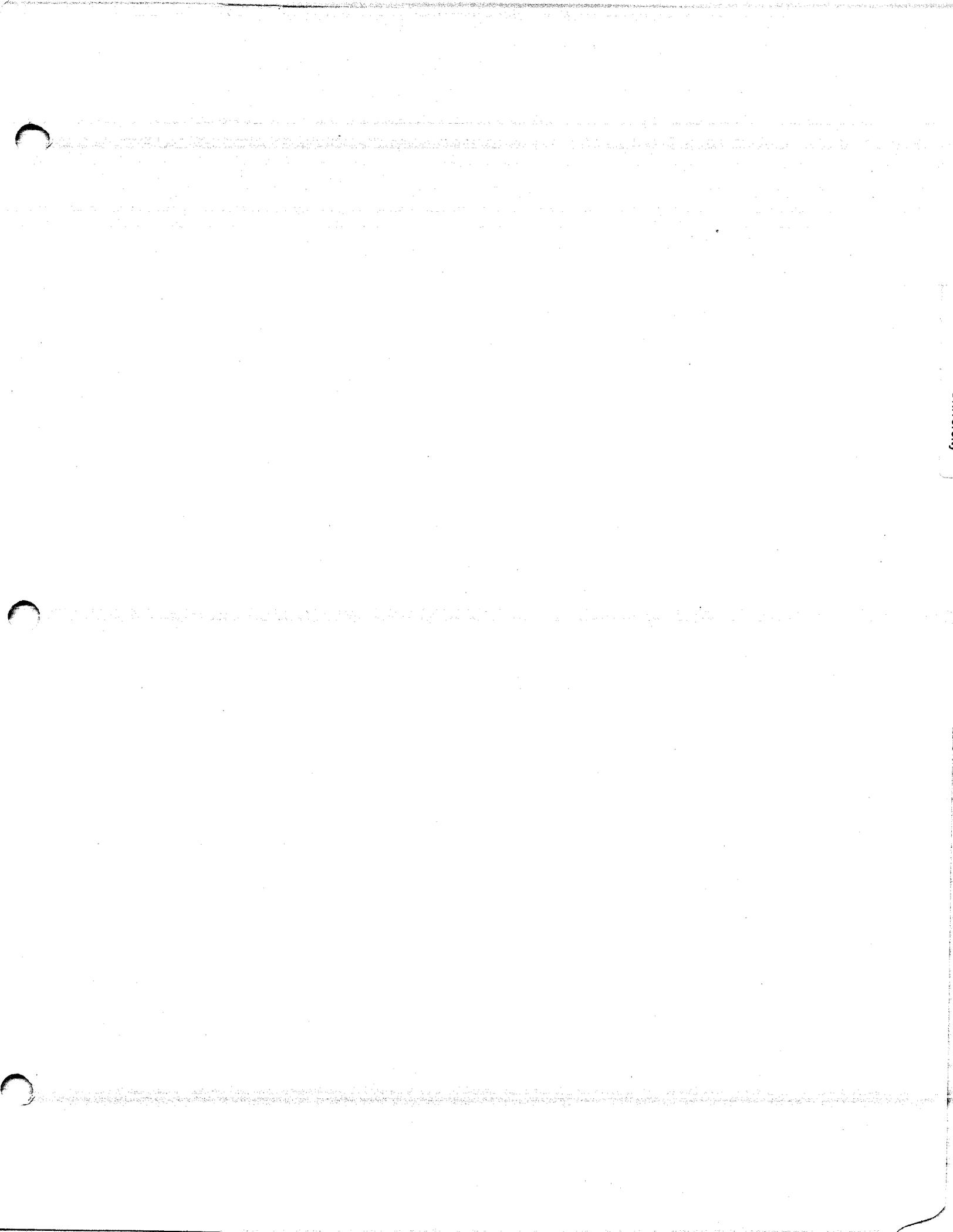
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Study of new drug to treat injured concluded

Vanderbilt University Medical Center recently participated in a research study to evaluate Hu23F2G, an investigational drug that may help severely injured patients. The drug acts on the white blood cells and may prevent them from causing damage to the body's major organs following trauma.

In order to determine the safety and effectiveness of this new drug, researchers studied 150 trauma victims at 11 trauma centers throughout the United States. In the clinical trial, some patients received Hu23F2G along with standard care and some patients received only the standard care for the severe injury.

Patients were enrolled into the study in one of three ways:

- patients gave their own informed consent if they were able;
- if a patient was unable to give consent, on arrival in the Emergency Department, hospital staff attempted to reach a family member, and, if successful, the family was asked to provide informed consent;
- if a family member was not located within three hours, the patient was enrolled under the FDA regulations waiving the requirement to obtain informed consent.

Efforts to locate and inform family continued after the patient had been enrolled into the study under the FDA regulations waiving the requirement to obtain an informed consent. Use of the FDA regulations waiving the requirement to obtain an informed consent in this study was approved

by the FDA and VUMC's Institutional Review Board, which is charged with ethical oversight of patient research at the medical center.

Enrollment into the study was completed in late January. At VUMC eight patients were enrolled into the study. None of the patients signed their own consent, all eight had a family member provide informed assent, and no patients were enrolled with a waiver of consent.

Nationally, 14 percent of patients signed their own consent, 53 percent had a family member provide informed consent and 33 percent were enrolled with waiver of informed consent.

Preliminary analysis of the study has been performed and Hu23F2G appeared to be safe in this patient population. A total of 11 patients nationwide, or 7 percent, died. The death rate was 10 percent in patients who received standard of care alone and 6 percent in patients who received Hu23F2G.

Although the endpoints that the study was designed to measure were no different between the patients who received standard of care and those who received the investigational drug along with standard of care, there was a suggestion that those patients who received the higher dose of Hu23F2G had decreased heart and lung failure compared with those patients who received standard care only. Further analyses of the data are under way.

Any questions about this study should be directed to Dr. John Morris at 936-0175. ■

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Trauma Study Results

Vanderbilt University Medical Center recently participated in a research study to evaluate an investigational drug that may help severely injured patients. The investigational drug being tested is called Hu23F2G (LeukArrest™). The research study is sponsored by ICOS Corporation (Bothell, Washington). Hu23F2G acts on white blood cells and may prevent them from causing damage to the body's major organs following trauma. In order to determine the safety and effectiveness of this new drug, researchers studied 150 trauma victims at 11 trauma centers throughout the United States. In the clinical trial, some patients received Hu23F2G along with standard care and some patients received the standard care for severe injury alone.

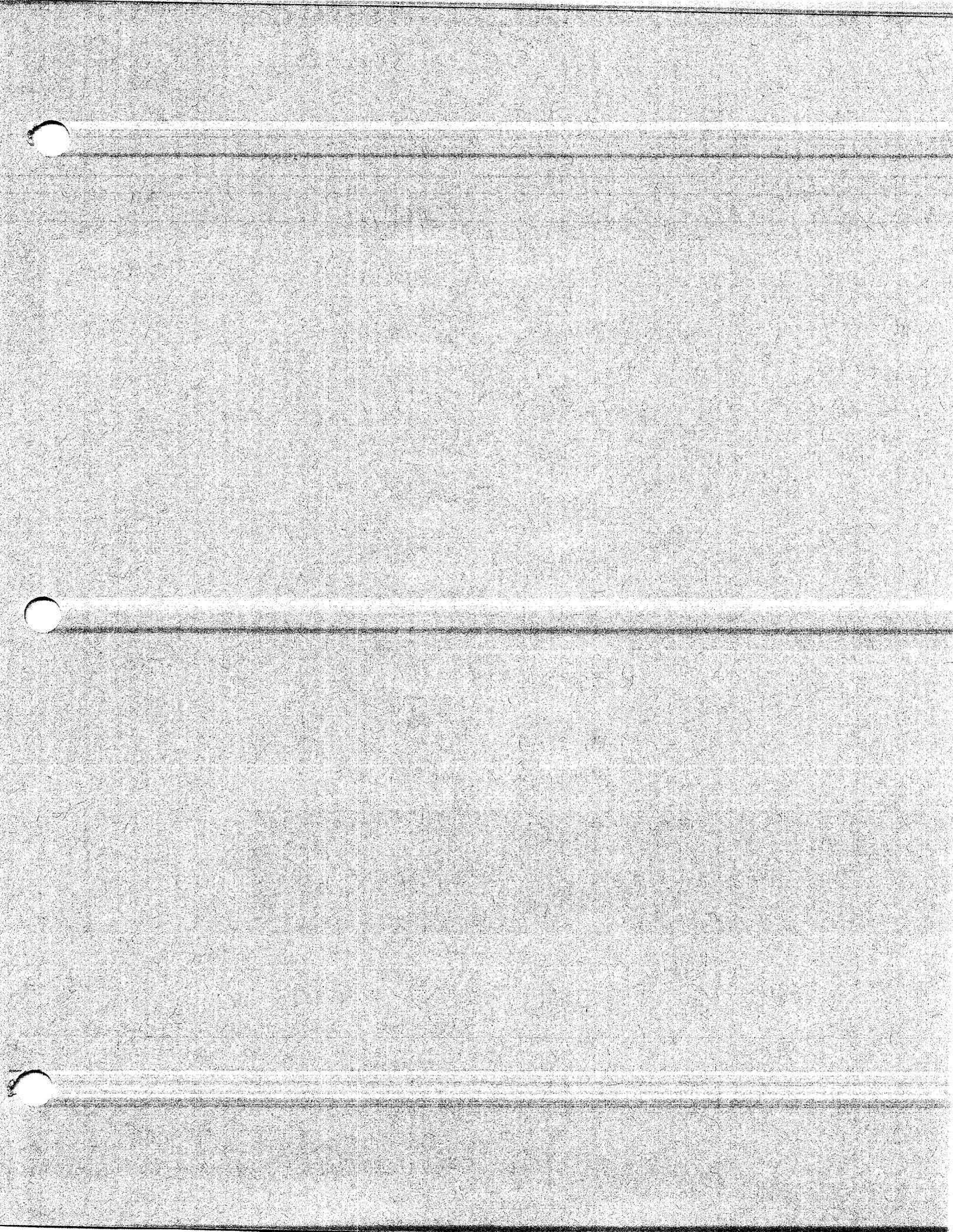
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Enrollment into this study was completed on January 26, 1999. Across the entire study, 14% of patients signed their own consent, 53% had a family member provide informed assent and 33% were enrolled with waiver of informed consent. At Vanderbilt University Medical Center, 8 patients were enrolled into the study from 12/19/98 to 1/25/99. No patients signed their own consent, 8 had a family member provide informed assent, and no patients were enrolled with a waiver of informed consent.

In this study, the average patient age was 36 years old, males were enrolled about twice as often as females. The majority of the patients were Caucasian (58%), followed by African American (25%) and other races (17%). At Vanderbilt University Medical Center the average patient age was 33 years old, 7 males and 1 female were enrolled. The majority of the patients were Caucasian (75%), followed by African American (25%).

Preliminary analysis of the study has been performed. Hu23F2G appeared to be safe in this patient population. A total of 11 patients (7%) died in the study. The death rate was 10% in patients who received standard of care alone and 6% in patients who received Hu23F2G. Although the endpoints that the study was designed to measure were no different between the patients that received standard of care and the patients that received Hu23F2G along with standard of care, there was a suggestion that those patients who received the higher dose of Hu23F2G had decreased heart and lung failure compared with those patients who received standard care only. Further analyses of the data are underway.

Any questions about this study should be directed to John Morris, MD at 615-936-0175



VUMC testing new drug to fight hemorrhagic shock

by John Howser

Vanderbilt University Medical Center's Division of Trauma is studying a new investigational drug designed to combat hemorrhagic shock.

The drug, Hu23F2G, will be tested in approximately 150 patients at 12 medical centers around the country in a waiver-of-consent study.

In cases of severe blood loss and shock after major injury, patients have about a 25 percent to 50 percent chance of dying with current treatments. One of the causes of death is damage to the heart, lungs, liver, and other organs caused by over-activity of

the body's white blood cells.

"We already have clinical experience looking at the inflammatory response process with another drug similar to Hu23F2G," said Dr. John A. Morris Jr., Director of the Division of Trauma, and the study's principal investigator. "What's new for us is that we will be studying this drug potentially under waiver of consent and that will allow us to get the drug to more individuals than in prior studies."

Hu23F2G is a humanized monoclonal antibody derived from human and animal pro-

Please see *SHOCK*, page 2

Advertisement ran in the VUMC Reporter on December 11, 1998.

Shock ...

Continued from front page

teins. It works by stopping white blood cells from sticking to the insides of blood vessels and causing damage. Sometimes when people are in shock, their white blood cells become too active and attack their own body. It's this increased activity of the white cells, usually brought about by very low blood pressure and decreased blood flow, which may lead to organ failure or death.

For Hu23F2G to work effectively it must be administered as soon as possible following injury. Patients chosen for the study will have the drug administered within three hours of arrival at VUMC.

Some severely injured patients that meet study criteria will be unable to give informed consent to participate in the study, and will not have family members immediately available to provide consent for them.

Food and Drug Administration (FDA) and Department of Health and Human Services (DHHS) regulations that went into effect on November 1, 1996 allow Vanderbilt's Institutional Review Board the authority to waive informed consent requirements in some acute care clinical investigations such as this.

"We are very encouraged that a drug like this may represent a breakthrough in our ability to reign in, or bring more under control, the inflammatory response associated with hem-



Donna Jones Bailey

VUMC's Division of Trauma is taking part in a multi-center study of a new drug to combat hemorrhagic shock.

orrhagic shock," he said.

Morris believes that Vanderbilt's typical trauma patient is at an even greater risk of death from hemorrhagic shock than patients at other level-one trauma centers around the country because of the large geographic area covered by LifeFlight.

"The risk of shock is probably higher at a place like Vanderbilt because we service such a large catchment area. Patients are coming to us having had this inflammatory response being initiated hours before they ever arrive," he said.

"Many trauma centers located in large cities have catchment areas covering a very small territory and control occurs much sooner."

For this reason Morris believes that Hu23F2G, or a drug with similar capabilities,

would be of greater benefit to Vanderbilt's patients and other patients from rural areas than perhaps a more urban patient population.

Morris says that the very patients that stand to benefit the most from an experimental drug like Hu23F2G are also the most difficult to enroll in an acute critical care study.

"LifeFlight can bring these patients here much sooner than their families can get here. The waiver of consent will allow us to match the patient population with the greatest need, i.e. the rural community, with a mechanism that will allow us to enroll them in the study," he said.

For questions regarding waiver of consent studies, please contact a representative of the Vanderbilt Medical Center Institutional Review Board at 322-2918. ■

Vanderbilt can study new drug

■ Hopes are to better survival chances for trauma patients

By **BILL SNYDER**

Staff Writer

Doctors at Vanderbilt University Medical Center have received permission to conduct an unusual study of a new drug that may improve survival among trauma patients.

What's unusual is that the drug, which studies suggest may reduce the damage done to the body by shock, will be given to severely injured patients without first getting their consent or the consent of their family members.

That's because the medication must be given within three hours after patients arrive at the emergency room. Many trauma patients are physically unable to give their consent, and in many cases their families don't arrive at the hospital until hours after lifesaving treatment has begun.

"This is a remarkably safe drug given our still-limited experience with it," said Dr. John A. Morris Jr., director of the division of trauma at Vanderbilt. "We get several hundred trauma patients a year who could benefit" from it.

Trauma — severe injuries suffered in accidents or assaults — is the leading killer of Americans ages 1-44.

When trauma causes severe blood loss, low blood pressure and decreased blood flow can occur, resulting in shock. These patients have a 25%-50% chance of dying — in part because of an inflammatory response to trauma that damages the body's internal organs.

White blood cells — which normally fight infections — mistakenly start attacking the body's own tissues, leading to inflammation, organ failure and death.

"What we all believe is, the earlier you can interrupt this damage ... the better the patients are going to do," Morris said.

The new drug, known only by the acronym Hu23F2G, is an antibody that has been made in the laboratory to attach specifically to white blood cells.

Animal studies suggest that the antibody can prevent the white blood cells from sticking to the insides of blood vessels and causing damage.

For it to be approved for wide use, however, testing cannot be limited to animals and the laboratory. "It's important for us to look at (it) in the real world as opposed to the test tube," Morris said.

That's why Vanderbilt is planning the unusual study.

In 1996, the U.S. Food and Drug Administration approved new rules that allow hospital review boards to waive informed consent requirements for studies involving desperately ill patients and potentially lifesaving therapy.

Last year, Vanderbilt's Institutional Review Board, which

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Vanderbilt to study new trauma drug

FROM PAGE 1A

patient research conducted at the medical center, approved a synthetic blood product for severely injured patients.

The study also waived the consent requirement.

The board has approved the preliminary study of the trauma drug, notification of the public.

For more information, or to submit comments about the study, call

the Institutional Review Board at 322-2918.

Each year, about 200 patients treated for trauma at Vanderbilt die from their injuries, medical center officials say.

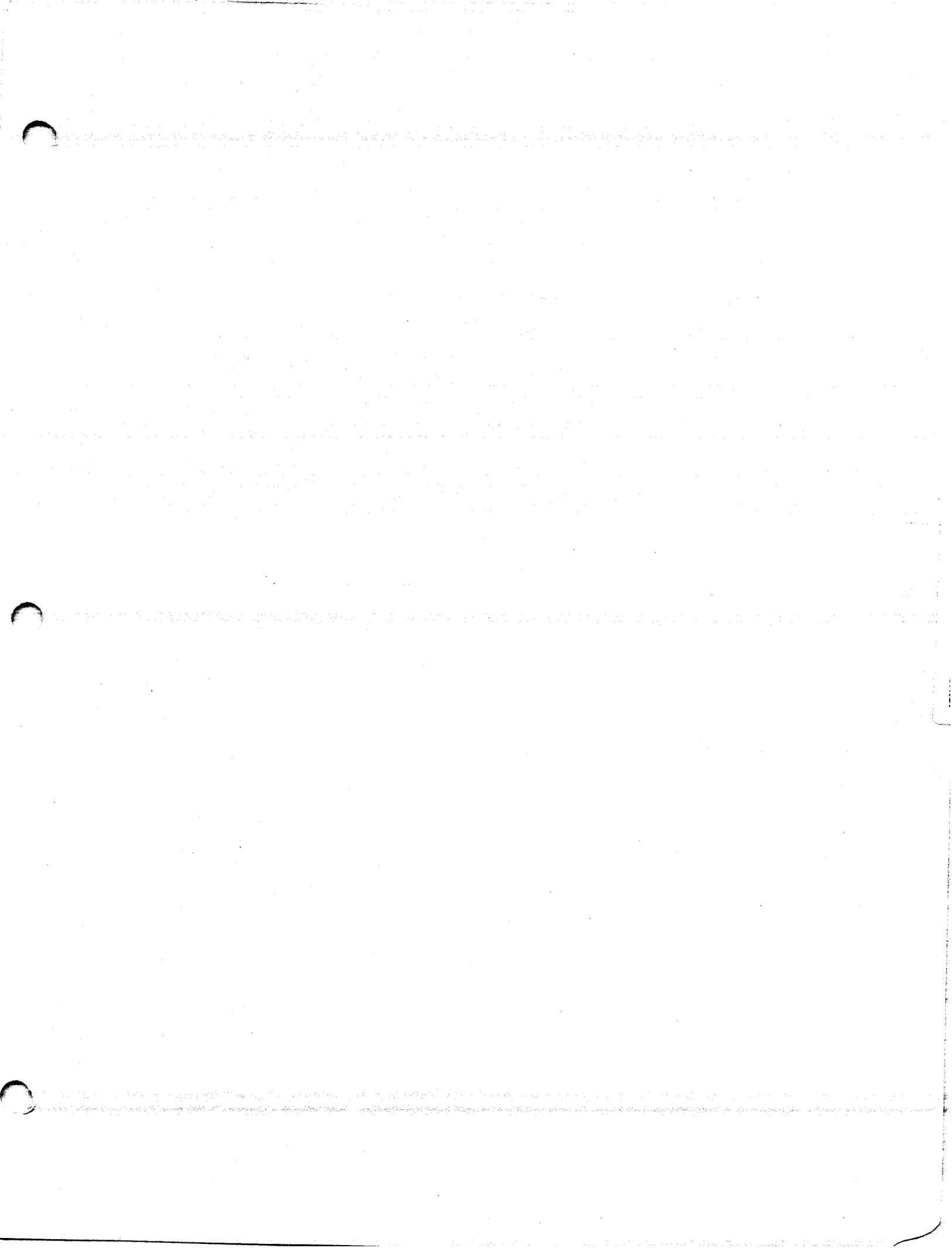
Vanderbilt has Middle Tennessee's only Level I trauma center, which treats the most severe injuries.

The leading causes of trauma deaths at Vanderbilt are motor vehicle accidents, followed by gunshot

wounds.

More than half of the 207 trauma patients who died at Vanderbilt July 1997-July 1998 were aged 15-45, medical center officials said.

Residents of rural areas are at significantly higher risk of dying from trauma, because it takes them longer to be brought to trauma centers like Vanderbilt's. They also may be most likely to benefit from the new drug, Morris said. ■



Advertisement ran in the Kansas City Star on November 10, 1999.

TRAUMA STUDY RESULTS

Truman Medical Center - West recently participated in a research study to evaluate an experimental drug that may help severely injured patients. The investigational drug being tested is called Hu23F2G (LeukArrest™). The research study is sponsored by ICOS Corporation (Bothell, Washington). Hu23F2G acts on the white blood cells and may prevent them from causing damage to the body's major organs following trauma. In order to determine the safety and effectiveness of this new drug, researchers studied 150 trauma victims at 11 trauma centers throughout the United States. In the clinical trial, some patients received Hu23F2G along with standard care and some patients received the standard care for severe injury alone.

Patients were enrolled into the study in one of three ways. First, patients gave their own informed consent if they were able. Second, if a patient were unable to give consent, then upon arrival in the emergency department the hospital staff attempted to reach a family member. If this was successful, the family was asked to provide informed assent. Third, if a family member was not located within three hours, the patient was enrolled under the Food and Drug Administration (FDA) regulations waiving the requirement to obtain an informed consent. The effort to locate and inform family continued after the patient had been enrolled into the study under the FDA regulations waiving the requirement to obtain an informed consent. Use of the FDA regulations waiving the requirement to obtain an informed consent in this study was approved by the FDA and the University of Missouri-Kansas City Adult Health Sciences IRB, which is charged with ethical oversight of patient research at Truman Medical Center - West.

Enrollment into this study was completed on January 26, 1999. Across the entire study, 14% of patients signed their own consent, 53% had a family member provide informed assent and 33% were enrolled with waiver of informed consent. At Truman Medical Center - West, 1 patient was enrolled into the study on 12/12/98. This patient was enrolled with a waiver of informed consent.

In this study, the average patient age was 36 years old, males were enrolled about twice as often as females. The majority of the patients were Caucasian (58%), followed by African American (25%) and other races (17%). At Truman Medical Center - West the patient age was 37 years and he was an African American male.

Preliminary analysis of the study has been performed. Hu23F2G appeared to be safe in this patient population. A total of 11 patients (7%) died in the study. The death rate was 5, (10%) in patients who received standard of care alone and 6, (6%) in patients who received Hu23F2G. Although the endpoints that the study was designed to measure were no different between the patients that received standard of care and the patients that received Hu23F2G along with standard of care, there was a suggestion that those patients who received the higher dose of Hu23F2G had decreased heart and lung failure compared with those patients who received standard care only. Further analyses of the data are underway.

Any questions about this study should be directed to Kendall McNabney, MD at (316) 556-3679.

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Advertisement ran in The Kansas City Globe on November 11, 1999.

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Trauma Study Results

Truman Medical Center-West recently participated in a research study to evaluate an experimental drug that may help severely injured patients. The investigational drug being tested is called Hu23F2G (LeukArrest). The research study is sponsored by ICOS Corporation (Bothell, WA). Hu23F2G acts on the white blood cells and may prevent them from causing damage to the body's major organs following trauma. In order to determine the safety and effectiveness of this new drug, researchers studied 150 trauma victims at 11 trauma centers throughout the United States. In the clinical trial, some patients received Hu23F2G along with standard care and some patients received the standard care for severe injury alone.

Patients were enrolled into the study in one of three ways. First, patients gave their own informed consent if they were able. Second, if a patient were unable to give consent, then upon arrival in the emergency department the hospital staff attempted to reach a family member. If this was successful, the family was asked to provide informed assent. Third, if a family member was not located within three hours, the patient was enrolled under the Food and Drug Administration (FDA) regulations waiving the requirement to obtain an informed consent. The effort to locate and inform family continued after the patient had been enrolled into the study under the FDA regulations waiving the requirement to obtain an informed consent. Use of the FDA regulations waiving the requirement to obtain informed consent in this study was approved by the FDA and the University of Missouri-Kansas City Adult Health Sciences IRB, which is charged with ethical oversight of patient research at Truman Medical Center-West.

Enrollment into this study was completed on January 26, 1999. Across the entire study, 14 percent of patients signed their own consent, 53 percent had a family member provide informed assent, and 33 percent were enrolled with waiver of informed consent. At Truman Medical Center-West, 1 patient was enrolled into the study on 12/12/98. This patient was enrolled with a waiver of informed consent.

In this study, the average patient age was 36 years old, males were enrolled about twice as often as females. The majority of the patients were Caucasian (58 percent) followed by African American (25 percent) and other races (17 percent). At Truman Medical Center-West, the patient age was 37 years and he was an African American male.

Preliminary analysis of the study has been performed. Hu23F2G appeared to be safe in this patient population. A total of 11 patients (7 percent) died in the study. The death rate was 5, (10 percent) in patients who received standard of care alone and 6, (6 percent) in patients who received Hu23F2G. Although the endpoints that the study was designed to measure were no different between the patients that received standard of care and the patients that received Hu23F2G along with standard of care, there was a suggestion that those patients who received the higher dose of Hu23F2G had decreased heart and lung failure compared with those patients who received standard care only. Further analysis of the data are underway.

Any questions about this study should be directed to Kendall McNabney, MD at 816-556-3679.

Advertisement ran in The Call during the week of November 12, 1999.

Truman Study Results

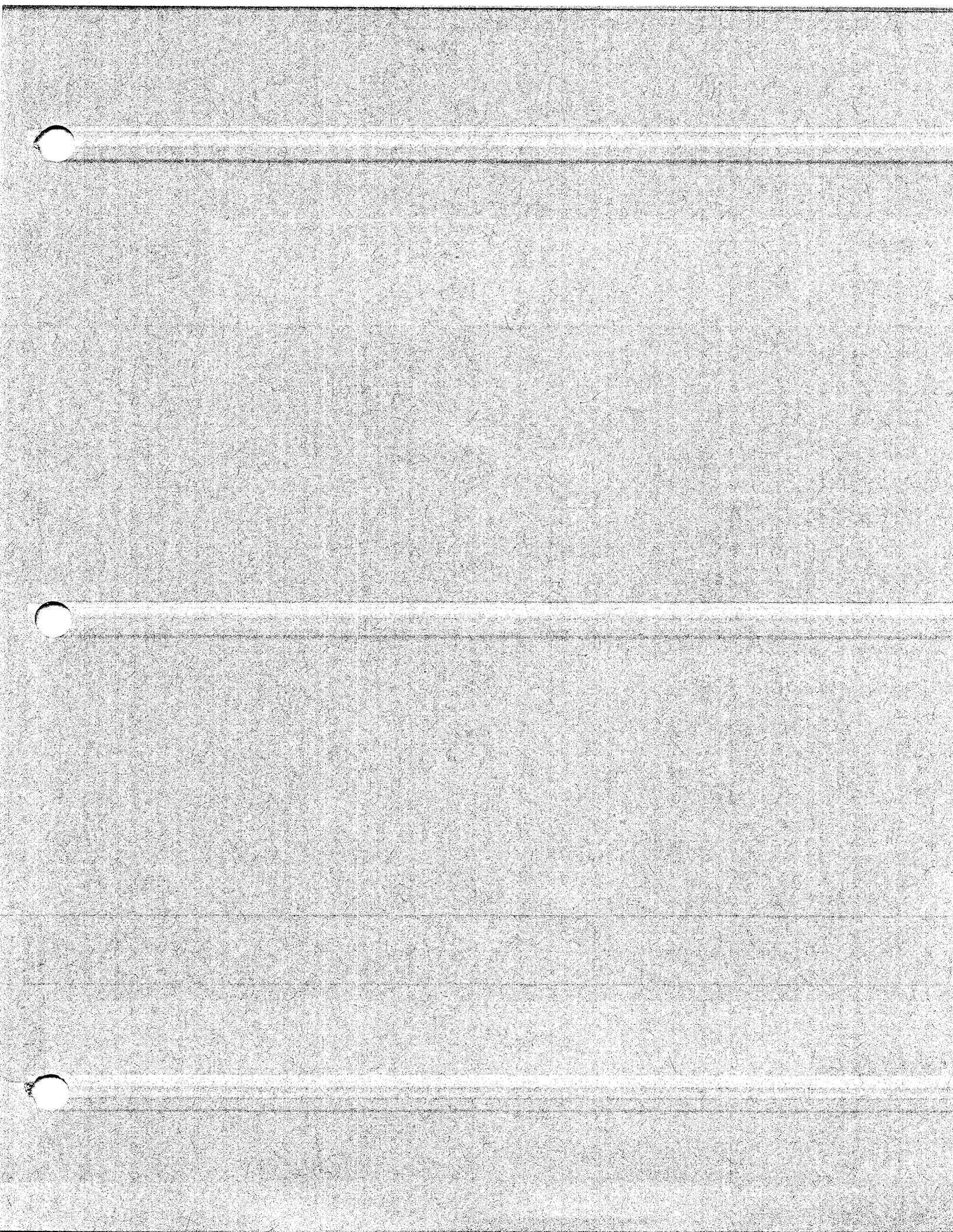
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TMC TO TEST EXPERIMENTAL DRUG

An important national clinical research study is happening at Truman Medical Center's Level 1 Trauma Center. Hu23F2G is an experimental drug which will be tested on randomly selected patients who have had a life threatening accident such as a car accident or gunshot wound. The research study which will be conducted under the guidance of the U.S. Food and Drug Administration, requires public notice because it will occur under emergency conditions that may require the study medication be given without informed consent.

WHY IS THIS TRIAL BEING PERFORMED?

Seriously injured patients frequently arrive at the hospital after losing a large amount of blood and are in shock. Despite the best care medicine has to offer, as many as 25-50% of the most critically injured patients will die from their injuries. One of the causes of death is damage to the heart, lungs, liver, and other organs caused by the white blood cells. Studies suggest that an experimental drug, Hu23F2G, may improve the chance of survival following severe blood loss. The product has the greatest chance of success if administered within the first three hours after injury.

WHY IS AN EXCEPTION FROM INFORMED CONSENT NECESSARY?

Because trauma patients are often so severely injured, they may not be able to give their consent to participate in the drug trial. Still, they are in critical need of immediate treatment. The U.S. Food and Drug Administration has established guidelines to grant an exception from informed consent in such cases. They have carefully evaluated Hu23F2G and determined that the potential benefits outweigh the risks of participating in the trial. As a result, patients may be enrolled in this study and receive Hu23F2G when informed consent is not possible.

We will make every attempt to obtain consent from patients, their legal representatives, or family before Hu23F2G is given. All patients and their family will be informed of their participation as soon as possible after enrollment. If informed consent is not possible, at all times, the patient or their representative may decline further participation in the study.

WHAT IS Hu23F2G?

Hu23F2G works on the white blood cells. Sometimes when people are in shock the white blood cells become too active and attack the body internally. This may cause the major organs, such as the lungs or liver, to fail and the person may die. Hu23F2G may work by stopping the white blood cells from sticking to the insides of blood vessels and causing damage.

WHAT ARE THE RISKS AND SIDE EFFECTS OF Hu23F2G?

Hu23F2G may increase the chance of infection. Patients will receive a strong antibiotic to minimize this potential risk. Hu23F2G has been studied in randomized trials involving more than 150 patients. Independent experts will monitor patient safety throughout the trial. Truman is participating in this drug trial because the potential benefits to seriously injured trauma patients may exceed known side effects of the treatment.

QUESTIONS OR COMMENTS?

We at Truman Medical Center are excited about the potential that experimental products, such as Hu23F2G, may have to save lives of severely injured patients. To provide comments or for more information about this product, please call (816) 556-3505 and ask to speak with Dr. McNabney.

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