

Witness Name: Debra Pollard
Statement No: WITN3094029

INFECTED BLOOD INQUIRY

EXHIBIT WITN3094032

This is the exhibit marked "WITN3094032" referred to in the statement of Debra Pollard no. WITN3094029.



The Royal Free Hampstead
NHS Trust

Pond Street
Hampstead
London NW3 2QG

Telephone
071-794 0500
Ext.

HAEMOPHILIA CENTRE AND HAEMOSTASIS UNIT

Dr P. B. A. KERNOFF, MD FRCP FRCPath
Director

Dr CHRISTINE A. LEE, MA MD FRCP MRCPath
Consultant Haematologist

July 26, 1991

Peter Squires

GRO-C

Dear Mr. Squires

Patricia Lilly has told me that you have agreed to kindly take part in a study of the new highly purified factor VIII concentrate. The study, and the enclosed patient information sheets have been approved by the hospital Ethical Committee. I thought you might like the information sheet now and then when you next attend the centre, we can discuss anything that is not clear or any questions you might have before your consent. We aim to begin the study at the end of August or in September on a day which suits you.

Thanks again for your help.

Sincerely

GRO-C

Dr. Michael Laffan
Locum Consultant



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CAL/MJ/01 52 83

19 November 1991

Dr S Dhar

GRO-C

MIDDX

Dear Dr Dhar

Peter SQUIRES - GRO-C 61

GRO-C

This patient who has severe haemophilia A, came for his six monthly review on 14th November. He is aged 30 and continues to work in a medical instruments factory.

He treats his haemophilia with 8Y and he has been suffering with a tremendous bout of bleeds. In his own words, he is getting "bleeds after bleeds", in particular in his left shoulder and ankles. This has been happening during the last three months since his holiday in the United States. He did have the impression that when he was in the 8Y/8SM study of fall offs, that 8SM seemed to be better. He is very reluctant however to have prophylactic treatment because of access problems.

As far as HIV is concerned, he is asymptomatic at present.

I also discussed with him, hepatitis C. He is infected with this virus but his ALT levels are not that abnormal, they are running around the 45 level. He would not qualify for Interferon treatment at this level.

He has never been vaccinated against hepatitis B, having had natural infection and the antibody level was greater than 100. He lives with his parents and he has his own car.

squires.cal

INFORMED CONSENT**EVALUATION OF TWO FORMULATIONS OF RECOMBINATE™:
COMPARISON OF ACUTE SAFETY AND PHARMACOKINETICS OF r-AHF
MANUFACTURED IN ANDOVER, MA AND THOUSAND OAKS, CA**

Before agreeing that I participate in this study, it is important that I read and understand the following explanation. It describes in words that can be understood by a lay person, the purpose, procedures, benefits, risks, and discomforts of the study and the precautions that will be taken. It also describes the alternatives available and the right to withdraw from the study at any time. I understand that refusal to participate will not influence the availability of standard medical treatment.

PURPOSE AND BACKGROUND

I understand that I have been asked to participate in a research study involving approximately 16 patients, sponsored by Baxter Healthcare Corporation, Hyland Division, Glendale, California. Patients with Hemophilia A have bleeding problems treated with clotting factor VIII. Baxter/Hyland Division in conjunction with Genetics Institute, Inc. has developed and marketed a recombinant clotting factor VIII (r-FVIII) known as Recombinate™. Currently, manufacturing of Recombinate™ is primarily done by Genetics Institute, Inc. in Andover, MA, USA. In order to increase the production of Recombinate™ to meet patient demand, Baxter/Hyland Division intends to manufacture Recombinate™ at a new production facility in Thousand Oaks, CA, USA. To be allowed to do this it is necessary that Baxter/Hyland Division prove that the product to be prepared in Thousand Oaks, CA behaves the same in Hemophilia A patients as the currently licensed Recombinate™, which is manufactured in Andover, MA.

PROCEDURES

My participation in this study is expected to last approximately 8 days. I will receive a total of two infusions of the study clotting factor VIII (Recombine™) during this study. Before participating in the study, a simple physical examination will be done and blood samples will be drawn for laboratory evaluation. Access to the vein will be maintained for approximately 3 hours. Immediately before and after each Recombinate™ infusion, my temperature, blood pressure, pulse, and respiration will be taken. Additional blood will be drawn after the start of each infusion to perform laboratory analysis. Over the next 24 hours, a total amount of approximately 4 tablespoons (63 ml) of blood will be drawn for this analysis. Seven days after the first study infusion, or seven days after I receive a study Recombinate™ treatment for a bleeding episode, I will receive the second study infusion.

12/1/95

of Recombinate™ following the same procedures as for the first infusion.

POTENTIAL BENEFITS

Participation in this study should prevent bleeds for approximately 24-48 hours after each infusion. However, this effect is not guaranteed. I may expect no other benefit from this study.

POTENTIAL RISKS AND DISCOMFORTS

The potential risks or discomforts to me may include:

1. Those associated with multiple venipunctures for blood testing and infusion of clotting factor VIII (Recombinant™).
2. The possibility of allergic reaction. This reaction could include changes in temperature, pulse, blood pressure, and/or breathing.
3. The possible development of resistance to clotting factor VIII (inhibitors). A similar risk exists with other factor VIII products.
4. The risk of viral transmission. I understand that to date, no episode of viral transmission has been shown to have occurred with this product.

Any significant new findings developed during the course of the study which may affect my willingness to continue participation will be provided to me.

ALTERNATIVE THERAPY

I understand that if I choose not to participate in this study, I will be given the institution's standard therapy for hemophilia A. I may discuss the alternative treatments available with the staff at the hemophilia center.

CONFIDENTIALITY

My medical records will be maintained in strict confidence to the extent permitted by law. I understand the FDA, other regulatory agencies, and Baxter Healthcare Corp./Hyland Division may inspect and copy medical records relating to this study. The results of the study will be reported to Baxter/Hyland Division, the FDA, and perhaps other regulatory agencies. The recipients of this information will treat this information confidentially, and in the event of any publication regarding the study, my identity will not be disclosed.

FINANCIAL ASPECTS

Reimbursement will be made available to me for costs generated by me for participation in this research study (such as travel, parking, etc.).

COMPENSATION

12/1/95

In the event I suffer an injury directly caused by the test drug/product or the study procedures or laboratory work required specifically by the protocol which defines the study in which I am participating, the costs of emergency treatment will be borne by Baxter Healthcare Corporation. The costs of any other medical care are my responsibility. No other compensation is available.

WITHDRAWAL FROM STUDY

My participation in this study is wholly voluntary. I fully understand that I may withdraw from the study at any time and for any reason, and that neither my decision to participate in the study nor any decision on my part will have any effect whatsoever on my medical care. I further understand that if my physician feels it is in my best interest to withdraw from the study, I will do so immediately. My participation may be ended at any time with or without my consent.

RIGHTS

I have talked with my physician about this study and he/she has answered my questions. If I have other questions, or suffer a study-related injury, I may call him/her at GRO-C. If I wish to speak to an impartial third party who is not associated with the study, I may contact IRB Ethics Committee at telephone number GRO-C. I have read this consent form and received a copy of it.

CONSENT

Before giving my consent by signing this form, I affirm that I have read it and spoken directly to the study physician who has answered to my satisfaction all of my questions concerning this study. Based on this information, I voluntarily agree to participate in this study. I will be given a signed copy of this consent form.

GRO-C: P Squires

Patient's Signature

11.2.97
Date

GRO-C: Christine Lee

Study Physician's Signature

11.2.97
Date

GRO-C

Witness (Optional)

11/2/97
Date