

Notes

HAEMOPHILIA AND HAEMOSTASIS UNIT

Extension GRO-C

PK/csc

1 December 1981

Dr. Michael Bennett,
Consultant Haematologist,
Oldchurch Hospital,
Romford,
ESSEX.

Dear Mike,

Gary REIDMAN

GRO-C

Many thanks for offering to help obtain serial blood samples from this 19 year old haemophiliac, who has a basal factor VIII level of around 6%.

Gary injured his right ankle in a fall about 10 days ago and, despite a dose of cryoprecipitate, experienced progressively severe pain and swelling around the joint. X-rays taken on 26.11.81 showed that a chip of bone was separated from the lower right fibula. There was some doubt whether this represents old injury, his present symptoms perhaps being due to ligamentous damage only.

In any event, his ankle was immobilised in a backslab and he was started on a course of factor VIII. Because of his size, the expected need for several days therapy, and the currently very poor quality of cryoprecipitate, we opted to use concentrate. So far as is known, Gary has not been treated with concentrate before.

Because of the high risk of non-A, non-B hepatitis following a first exposure to concentrate, we are assessing the effects of a preparation made for us by Immuno (Kryobulin G) which contains added immunoglobulin. Gary had a five day course of this from 26.11.81 to 30.11.81. We should like to do conventional liver function tests and special immunological tests at weekly intervals for the next seven weeks and then every two weeks until the end of July 1982. This is to be sure of detecting any sub-clinical infection.

As discussed, I have asked Gary to call in to see you on Monday 9th December at 1.30pm. Thereafter, the times and dates of blood sampling can be at your mutual convenience. The attached schedule shows when samples are needed. 10mls of heparinised blood are needed for conventional liver function tests, and a further 10 or 20mls of blood should be taken into a plain glass tube for serum. If the LFTs can be done at Oldchurch, so much the better. The separated serum should be deep-frozen, if possible in 2ml aliquots. We can arrange for transfer of these serum samples at a later date.

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BLOOD SAMPLES NEEDED FROM GARY REDMAN

10ml blood into heparin for LFTs

2 x 10ml blood into plain glass, allow to clot,
separate serum, store in 2ml aliquots deep-frozen.

DATES OF SAMPLES:

Week starting:	Wednesday 9 December 1981	Oldchurch	1.30pm
	14 December	:	
	21 December	:	
	28 December	:	
	4 January 1982	:	
	11 January	:	
	1 February	:	
	15 February	:	
	1 March	:	
	15 March	:	
	29 March	:	
	5 April	:	
	19 April	:	
	3 May	:	
	17 May	:	
	31 May	:	
	14 June	:	
	28 June	:	
	12 July	:	
	26 July	:	

Gary REDMAN (continued)

If Gary needs further treatment with factor VIII, over the next nine months, it is important that he receives the same preparation of Kryobulin G. If he becomes symptomatic, or his LFTs show changes suggestive of sub-clinical infection, then perhaps we could liaise by 'phone?

With all best wishes,

Yours sincerely,

P. B. A. Kernoff, MD., MRCP.
Consultant Haematologist

s.o. Sister Patricia Lilley

Barking and Havering Area Health Authority

E.9 FEB 1982

OLDCHURCH HOSPITAL

Romford, Essex RM7 0BE
Dept. of Haematology

8th February 1982

ref: MB/JT/ 426002

telephone: Romford GRO-C

telephone extn.

GRO-C

Dr. Peter Kernoff
Consultant Haematologist
Royal Free Hospital
Haemostasis Unit
Grosvenor Street
NW3

Dear Peter,

re: Gary Redman, DOB GRO-C

I am enclosing as promised results of liver function tests on Gary Redman.

I saw him recently. He was asymptomatic but on examination was icteric. Liver and spleen were impalpable.

We are continuing to do liver function tests and save serum, as on your chart.

I have made arrangements to see him again on the 1st March.

Yours sincerely,

GRO-C

M. Bennett, M.B., MRCP., MRC.Path
Consultant Haematologist

HAEMOPHILIA AND HAEMOSTASIS UNIT

Extension GRO-C

PK/csc

10 February 1982

Dr. Michael Bennett,
Consultant Haematologist,
Oldchurch Hospital,
Romford,
ESSEX.

Dear Mike,

Gary REDMAN

GRO-C

Very many thanks for all your trouble and sending the IFT results. Gary's acute hepatitis seems very typical of non-A, non-B transmitted infection, although I will delay doing serology until we have several months' samples.

Although it's a bit disappointing that the acute attack wasn't prevented, we are also interested in the question of chronic changes, hence the reason to continue testing as per the protocol.

I gather that Sister Denise Blake, the new Haemophilia Co-ordinator for NETR, will be calling in to see you soon. It would seem easiest for Denise to pick up any samples and results when she calls, rather than going to the trouble of sending them.

With all best wishes,

Yours sincerely,

P. S. A. Kernoff, MD., MRCP.
Consultant Haematologist

HAEMOPHILIA AND HAEMOSTASIS UNIT

Extension GRO-C

PK/cac

16 December 1981

Mr. Norman Berry,
Managing Director,
Immuno Limited,
Arctic House,
Rye Lane,
Dunton Green,
Mr. Sevenoaks,
KENT.

Dear Mr. Berry,

Gary REDMAN

GRO-C

My apologies for not sending you details about this patient whom we recently treated with Factor VIII-G.

Mr. Redman has mild haemophilia (basal factor VIII level 6iu/dl) and has been under our care since 1973. Since this time, he has needed treatment once or twice a year, generally for bleeding episodes which have followed trauma. Treatment has always been with cryoprecipitate, and I estimate his total life-time donor exposure to be about 200. He has never had clinical hepatitis and his liver function tests have never been known to be abnormal.

On 22.11.81, Mr. Redman injured his right ankle in a fall. Despite having a dose of cryoprecipitate on 23.11.81, he experienced progressively severe pain and swelling around the joint. X-rays taken on 26.11.81 showed a small chip of bone had been separated from the lower right fibula and Mr. Redman was therefore admitted to hospital for a few days for more intensive treatment with factor VIII and immobilisation.

Because the anticipated requirements for factor VIII were greater than could be coped with using cryoprecipitate, and because Mr. Redman had never previously received concentrate and was therefore at high risk of post-transfusion hepatitis, we opted to use factor VIII-G. This was initially infused at the rate of 2ml/min but because of the complete absence of any adverse effects, the rate was increased for subsequent infusions. No dose was given in a period shorter than 15 minutes. Pulse rate, temperature and symptoms were monitored at frequent intervals for at least four hours after each infusion.

Mr. Redman's course of therapy was as follows:

23.11.81	20.00	Cryo x 15
26.11.81	12.00	Factor VIII-G 1/81 x 10 = 2490 u
		Pre 21 iu/dl Post 96iu/dl
26.11.81	22.00	Factor VIII-G 1/81 x 6 = 1494
27.11.81 q	09.30	" " " " "
		Pre 50 iu/dl Post 85 iu/dl
27.11.81	21.30	Factor VIII-G 1/81 x 6 = 1494
28.11.81	10.00	" " " " "

Gary Redman (continued)

29

29.11.81 10.00 Factor VIII-G 1/81 x 20 = 1992
30.11.81 11.00 " " " " x 4 = 996

Total number of infusions of Factor VIII-G: 7

Total number of vials Factor VIII-G: 46

Total number of units Factor VIII-G: 11,454 = 164 u/kg

Total immunoglobulin dose @ 635mg/vial: 29,210 mg = 417mg/kg

Pre-infusion liver function tests on 26.11.81 and 30.11.81 were normal, and Mr. Redman is negative for HB_e antigen/antibody. We intend to follow his liver function tests and serology at frequent intervals over the next few months, so far as possible in accord with the protocol for this study. I shall let you know what transpires.

It would be very helpful, as we discussed, if you could let me have details about the source plasma and donor pool size used to prepare the factor VIII and immunoglobulin.

With kind regards,

Yours sincerely,

P. B. A. Kernoff, MD., MRCP.
Consultant Haematologist

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10 February 1982

Mr. Norman Berry,
Managing Director,
Immuno Limited,
Arctic House,
Rye Lane,
Dunton Green,
Nr. Sevenoaks,
KENT

Dear Mr. Berry,

Gary REDMAN: Factor VIII - G

I'm afraid that factor VIII - G does not seem to have prevented Gary Redman contracting acute hepatitis. The enclosed graph shows the change in AAT over the last three months. You will see that Mr. Redman got a rather typical attack of post-infusion hepatitis with an incubation period of about four weeks. We do not have any serology yet, but I am sure this will turn out to be overt non-A, non-B variety.

While this is a bit disappointing, it is by no means the end of the story. It will also be important to know whether the acute attack progresses in a typical fashion to chronicity, and for this reason, we shall continue to obtain samples from Gary at 2-weekly intervals until July at least. I shall send you periodic up-dates on the position.

We still of course intend to use the material in other patients. The most likely candidate at this stage seems to be Matthew Derriman.

I wonder if you have yet got any information on the donor pool sizes of the factor VIII and immunoglobulin?

With kind regards,

Yours sincerely,

P. B. A. Kernoff, MD., MRCP.
Consultant Haematologist