for NOTES

AN OPEN STUDY TO ASSESS THE SAFETY, EFFICACY AND ECONOMICS OF THE USE OF MONOCLATE-P BY CONTINUOUS INFUSION IN PATIENTS WITH HAEMOPHILIA A UNDERGOING MAJOR SURGERY OR SUFFERING MAJOR HAEMORRHAGIC EPISODES

Principal Investigator KJ PAS

Subject's Name GRO-B

PATIENT INFORMED CONSENT STATEMENT

A. Purpose and Benefit

You have been asked to be in a research study to test the safety and usefulness of a specially treated factor VIII product called Monoclate-P, given to you continuously during your operation/major bleed and for up to 5 days afterwards.

Factor VIII is the blood clotting substance essential for the normal clotting of the blood and which is absent or abnormal in people, like you, who have Haemophilia A.

Monoclate-P is made by a special process which is thought to make it more pure than other factor VIII products currently available.

In patients with Haemophilia A, Monoclate-P and other factor VIII products are routinely used to control major bleeds and bleeding associated with surgery. The injections are usually given at intervals each day, often in the morning and evening time. During surgery and afterwards, additional injections are sometimes required.

The purpose of this study is to test the effectiveness and safety of Monoclate-P during and after surgery or a major bleed when given by continuous injection from a miniature pump or transfusion bag.

Possible benefits will be a reduction in the risk of bleeding between intermittent injections when the factor level falls, and the reduction in the need for repeated injections throughout surgery and during the post-operative period.

B. Study Procedure

If you agree to take part in this study, you will receive Monoclate-P as needed for replacement treatment during your hospitalisation for your operation or acute severe bleed. The study drug will be mixed with a diluent, and given as an initial infusion into your vein before the operation starts. Thereafter, the study drug will be given slowly and continuously into a vein throughout the operation and for about five days afterwards. The infusion may be given from a mini-pump or an infusion set. Sterile saline will be mixed with the Monoclate-P continuously to reduce the risk of local irritation to the vein. If needed, you may be given one or two extra infusions, should your blood levels of factor VIII fall quicker than expected.

Initially, shortly after your first injection and approximately once a day thereafter, a sample of blood will be drawn to measure your factor VIII levels in the blood. This is needed to adjust the speed of the pump or factor VIII drip to maintain high factor VIII levels continuously throughout the operation and while you are recovering. The site of injection will be carefully watched and any blood lost during the operation measured.

C. Risks and Discomforts

It is possible that you may have some discomfort at the injection site, and blood tests taken from your arm may cause some pain from the needle, and there could be some bruising or bleeding.

As with any blood product, there are risks of viral infection such as hepatitis or AIDS or a transfusion reaction (such as chills, fever, hives, itching). However, Monoclate-P has been shown to be safe in people with Haemophilia A during the use of over 150 million units. Monoclate-P has been pasteurized, a process that has been shown to remove AIDS and other viruses.

As with all factor VIII preparations, there may be a risk of severe reactions such as low blood pressure (shock), wheezing, high fever with chills or chest and back pain. Since Monoclate-P may contain traces of mouse protein used in the purification process, an allergic reaction is theoretically possible, though none have been reported to date.

D. Participation and Confidentiality

As a volunteer, you will be joining this study of your own free will and without any kind of pressure. You are free to withdraw from the study at any time, before or after it starts. If you decide you don't want to stay in the study, you must simply tell your doctor, the investigator, or the study staff and they will tell you what to do. If you withdraw from the study, there will be no disadvantage or prejudice to your subsequent treatment. You may be advised to have some more tests done if the physician thinks that would be best for you. The physician may take you out of the study if it is in your best interest with or without your consent. The whole study could be stopped or cancelled by the sponsoring company.

New information about Monoclate-P could come up that might affect your decision to begin or continue in this study. Your doctor will advise you of any new findings if they occur.

Your medical records and the information collected in this study may be reviewed by employees of the Clinical Research Department of Armour Pharmaceutical Company Limited. All information about you in this study will be handled with the strictest confidence. If the results of this study are published for scientific purposes, your name will not appear and no one will know your identity.

E. Injury

If you are injured as a result of being in this study, the medical care given to you related to treatment of that injury will be paid for by the sponsoring company who have an insurance policy covering the risks of this clinical study. All claims will be dealt with according to the Association of British Pharmaceutical Industry guidelines on no fault compensation

F. Information

Any questions you have about this study will be answered by Dr. J. Pasi or one of his research staff. The doctor may be reached by phone at _____.
If you have any questions about your rights as a research subject or about an injury related to the study, you should contact _____(name)

at _____(phone number).

G. Volunteer's Statement

I am satisfied that I have been told about benefits and risks of being in this study. I have read this consent form and I understand it. I have been given a chance to ask questions about this study and they have been answered to my satisfaction. I am signing this form of my own free will. I am not being forced to do it and my participation in this study is voluntary.

I have been offered a copy of this consent form to keep for my records.

GRO-C

_____ _____
Signature of Patient (if over age 16)
Parent or Legal Guardian

Date

GRO-C

_____ _____
Signature of Witness

17/6/15
Date

GRO-C

_____ _____
Investigator's Signature

Date