Understanding and managing the coagulopathy of APL

Patient information Leaflet

We would like to invite you to take part in this study, which is research to look into blood coagulation abnormalities in Acute Promyelocytic Leukaemia (APL). It is optional to take part and it will not affect your treatment in any way if you decide not to. If you do agree, an extra sample will be taken on some of the days when you have a blood test.

Background

You have been selected to take part in this study because you have recently been diagnosed with Acute Promyelocytic Leukaemia. Most people with this disease develop significant abnormalities with their blood clotting, especially when the disease first comes on and when treatment is started.

In general the treatment for Acute Promyelocytic Leukaemia is quite advanced, and has a very high cure rate. This means that the blood clotting abnormalities are now the most dangerous aspect of this condition, and can lead to both severe bleeding and blood clots.

We would like to find out more about why the blood coagulation is so abnormal in APL, this may lead to better ways to treat it and prevent complications.
What will happen to me if I take part?

An extra two small tubes of blood will be taken from you at the same time as your routine blood tests, you will not have to have an extra needle. These will be taken before you start treatment, and then every third day until you get discharged from hospital. The samples will be sent to Guy’s and St Thomas’ Hospital, where several different tests will be done to look at blood coagulation. We will also use part of a blood sample that has already been taken from you and is stored in the hospital laboratory. Normally this would be thrown away after a few days but we would like to use it for this research.

The samples will be only identified by a code number. None of your personal details will be passed on or stored. The results of the tests will not be sent to your doctor, and will not be used to plan your treatment.

What if I don’t want to take part?

You do not have to take part in this study; if you agree to take part and change your mind you can withdraw at any time by informing the doctors or nurses looking after you. You do not have to give a reason for not wanting to take part or for withdrawing from this study, and it will not affect your medical care or treatment in any way.

Contact for Further Information

Further information can be obtained from your local organiser (Principal Investigator) or the UK organiser (Chief Investigator) whose addresses are given below.

Chief Investigator:
Prof Beverley Hunt
Haematology Department
4th Floor North Wing
St Thomas’ Hospital
Westminster Bridge Road
London SE17EH
CONSENT FORM

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(Please initial)

1. I have read the attached Information Sheet version 1 (January 2012) □

2. I have had an opportunity to discuss this study and ask questions □

3. I have received satisfactory answers to all of my questions □

4. I have received enough information about the study □

5. I have spoken with Dr./Mr./Ms. ___________________________

6. I understand that I am free to withdraw from the study:
   • at any time □
   • without having to give reasons □
   • without affecting my future medical care □

7. I agree to participate in this study □
Patient’s Signature:_____________________________________

Name in block letters:___________________________________

Date_____________________

Doctor’s Signature:_____________________________________

Name in block letters:___________________________________

Date_____________________

Patient Representative’s Signature:_______________________
(if appropriate)_________________________________________

Name in block letters:___________________________________

Relationship to patient:_______________________________

Date_____________________

Patient Information and Consent form, Version 2, February 2012

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