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PATIENT INFORMATION SHEET

Study title: Bone marrow function in normal subjects and in patients being investigated for a possible blood cell abnormality

Introduction

You are invited to take part in a research study looking at how blood cells are made and what happens when this goes wrong. Your doctor thinks you require a bone marrow test to help decide whether or not you have a blood disorder. If any of the bone marrow and blood samples are left over after your doctor has used what is required, we would like to ask your permission to use these remaining samples for research purposes.

Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information sheet. Do talk to others about the study if you wish.

Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. This leaflet describes what the research is about and what it would involve for you.

Background

Blood is composed of blood cells and plasma. There are several different types of blood cell and each of these types have important jobs. For example, red cells carry oxygen around the body, to provide energy. White cells help you to fight infection whilst cells called platelets stop you from bleeding and bruising.

Blood cells are made in the bone marrow. They start life as immature cells called stem cells, which eventually will develop either into red cells, white cells or platelets. Several important blood disorders can occur if this process goes wrong. For example, some people

don't make enough white or red cells or platelets. What controls the development of stem cells into different types of blood cells is not fully understood. We do know, however, that it must have something to do with the genes within the stem cell. Literally thousands of genes must be turned on or off in the right order for the stem cell to develop normally into a mature blood cell. We would like to find out more about the "program" of how genes control this process.

What is the purpose of the study?

The aim of this study is to examine the genetic programs in normal and abnormal bone marrow cells in order to deduce how blood cells are made and to find out what happens when things go wrong.

Why have I been selected?

Your doctor thinks you might have a blood disorder and as part of the investigation of this he feels that it is necessary to take a bone marrow and blood sample. With your agreement we would like to use any bone marrow and blood sample that is left over for research purposes.

Will any additional discomfort be involved if you take an extra sample of bone marrow or blood?

No as we would like to use any left over bone marrow and blood from the sample that you will have to have taken.

What will happen to my samples once they have been taken?

Your doctor will use some of the marrow sample to help him make a diagnosis. Left over sample will be sent to the laboratory in Oxford where we will separate out the bone marrow cells. Some of your bone marrow cells will be grown in the laboratory to see how well they develop into red cells, white cells and platelets. We will use the remaining cells to extract genetic material. We will examine this material to see which genes have been turned on and which genes are turned off.

We will check your blood sample to see how well you are making red cells, white cells and platelets.

What will happen to my sample after the study has finished?

If you agree (Part B of the consent form), when we have finished this study we would like to keep any remaining genetic material from your samples. The reason for this is that there may be other research studies in the future for which this material would be helpful in advancing our understanding of blood disorders. Samples kept in this way would be stored securely at the Weatherall Institute of Molecular Medicine under the custody of Dr Paresh Vyas and Dr Alex Sternberg on behalf of the Medical Research Council UK. The samples kept for storage would be totally anonymised so that they could not be traced back to you and would only be used for studies approved by a research ethics committee. If you would rather we did not store your sample, we would discard it at the end of the present study

Will my taking part in this study be kept confidential?

All information that is collected about you during the course of the research will be kept strictly confidential. Information about your blood disorder will be shared with the doctors in Oxford. Any information about you that leaves the hospital will have your name and address removed so that you cannot be recognised from it. In Oxford, your information will be given a unique number and will be stored on a computer. Access to your information will be coded and protected by a password. Only the doctors directly involved with the study will be able to see the information.

What kind of information about me will you collect?

If you agree to take part, we will ask your doctor to state any major health problems you have had now or in the past. After that, we will collect information regarding your blood tests and symptoms or treatments that may relate to your blood. This information will be collected and securely stored on a computer in Oxford every three months for as long as you are under the care of the haematology department.

Are there any other tests or aspects of this study I have committed myself to?

There are no additional tests. It does not entail any additional hospital visits. However, should your doctor think you require monitoring with additional bone marrow biopsies in future, we will be sent a sample.

Do I have to take part?

No. If you do not wish to participate in this study you may do so without justifying your decision and your future treatment will not be affected.

How will taking part help me?

There will be no direct medical benefit to you but we hope that this research will help patients in the future.

Can I find out the results of the research on my sample?

No. Unfortunately we will not be able to discuss the results from individual samples. When the research is complete, we will send a summary of our findings from all the samples taken to your consultant /research nurse so that they may be passed on to you.

What do I do next?

If you would like to participate in this study, please fill in and return the enclosed consent form to one of the haematology team.

If you require further information, please do not hesitate to contact Dr. Sternberg on (01865 222410) or Dr Vyas (01865 22309) or speak with your Consultant.

Thank you for taking time to read this leaflet.

Dr. Alexander Sternberg
Consultant Haematologist

Dr. Paresh Vyas
Consultant Haematologist