

# **MRC CLL5 STUDY: PATIENT INFORMATION SHEET**

*26 Sept 2001*

## **A Medical Research Council prospective randomised study to compare autologous stem cell transplant versus no further treatment in patients with high risk chronic lymphocytic leukaemia who have achieved a good response to treatment**

### **Introduction**

You are being asked to take part in a multi-centre randomised trial that is being conducted in many hospitals throughout the UK. It is run through the Medical Research Council and has been subject to ethical approval by your local hospital. This UK trial is part of a larger study taking place across Europe which is co-ordinated by the European Bone Marrow Transplant Group.

Before you decide whether or not to take part, 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 carefully and discuss it with friends, relatives and your GP 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.

### **Background**

Chronic lymphocytic leukaemia (CLL) is the most common adult leukaemia in western countries. It is a disease that affects the blood, lymph glands and bone marrow. You have high risk CLL which means that your life expectancy is shorter than it is for people without CLL. You have had a good response to treatment, but chemotherapy only rarely makes all the biological signs of the disease disappear. The current standard is that no further treatment should be given now even though some of these signs may still be present. It is very likely that the disease will recur at some point and autologous stem cell transplantation (a transplant using cells from your own body rather than from a donor) is often given then, as it can lead to the disappearance of all biological signs of the disease. With an autologous transplant

certain cells in your own blood (called stem cells) are collected. You are then given high doses of chemotherapy and radiotherapy to destroy the remaining traces of leukaemia in your body. This also damages your body's healthy cells, but the collected cells are transplanted back into your bone marrow to help it recover. Currently we do not know if it would benefit more patients if autologous stem cell transplantation was given at the earlier stage that you are now at, rather than waiting until the CLL has progressed.

This trial is a comparison between no further treatment at present and an autologous stem cell transplant. Whether or not you receive a transplant will be selected by a process called randomisation. That is, it will not be chosen by you or your doctor but by a computer and it is like the toss of a coin. This is to prevent bias in the results of the trial. You have a fifty-fifty chance of being put in the autologous transplant group. We need about 300 patients with high risk CLL to participate in the trial for us to be able to tell reliably if autologous transplantation at this stage makes a difference to survival. Patients in the "no further treatment at present" group can still receive an autologous transplant at a later stage.

### **Do I have to take part?**

It is up to you to decide whether or not to take part. If you decide to take part you will be asked to sign a consent form and given a copy of both it and this information sheet to keep. If you decide to take part you are still free to change your mind or withdraw at any time and without giving a reason. This will not affect the standard of treatment or care you receive. Your legal rights are not affected by giving your consent to take part in this study.

### **What does the trial involve for me?**

If you agree to take part in this study you will be asked to have a clinical examination, blood tests, a chest x-ray, a heart function test and tests to see how well your CLL is being controlled (blood tests and a bone marrow biopsy).

You will then be randomised to either autologous transplantation or simple surveillance of the disease. After randomisation you will have a course of

chemotherapy and we will remove stem cells from your blood (called harvesting) ready for use in an autologous transplant. This will be carried out even if you are put in the no further treatment group, for use if your disease progresses. In all cases your doctor will need to see you regularly to monitor your disease. A clinical examination, and blood tests will be done at each visit, which should be every 4 months in the first year and then every six months for the two following years. If you have a transplant then a bone marrow sample will also be needed every 4 months in the first year and then at six month intervals. Some of the blood and bone marrow samples will be used for medical research. You will also be asked to fill in a quality of life form at entry into the trial and at 4, 8, 12, 24, 36 and 48 months after this. It only takes a few minutes to complete and gives us valuable information about how your every day activities are affected by your disease and treatment.

	Randomisation	4 mths	8 mths	1 year	18 mths	2 years	30 mths	3 years	4 years
Blood test	Y	Y	Y	Y	Y	Y	Y	Y	Y
Bone marrow*	Y	Y*	Y*	Y*	Y*	Y*	Y*	Y*	Y*
Quality of life form	Y	Y	Y	Y		Y		Y	Y

\* Bone marrow samples other than the first one are requested only from patients receiving transplant.

**What are the possible side effects?**

The chemotherapy that you have already received has some side effects. The most common effects are

- a reduction in white blood cells which can be accompanied by fever and may require an antibiotic treatment
- a reduction in red blood cells (anaemia) which can cause fatigue and may require blood transfusion
- a reduction in blood platelets which may cause bleeding and require transfusions of platelets

The other side effects that can occur are nausea, vomiting, sores and problems with sensitivity in the lower limbs. There is a high risk that you will temporarily lose your hair.

Autologous transplantation and the high dose chemo- and radiotherapy that precede it also have side effects similar to those listed above, most common is an increase in the risk of infection both during and after the procedure. Irritation to the lining of the mouth and gullet is common (mucositis) and lasts about 7 days. The transplant will only be carried out in centres experienced in this type of treatment. Normally the blood count will recover in 14 days and patients can expect to be in hospital about three weeks for the autograft procedure. There is also a risk that transplantation can lead to death. In CLL the risk could be as much as 10%.

**After autologous transplantation there is a high risk of permanent sterility therefore men will be given the opportunity to have sperm frozen. At present there is no generally available method for freezing the eggs of women although it is sometimes possible to freeze embryos. Your doctor will discuss these issues with you. It is possible that if a woman is pregnant when given a transplant it will harm the unborn child. Pregnant women must not therefore take part in this study, nor should women who are breast feeding as this may also be harmful to the child. Women who are at risk of pregnancy may be asked to have a pregnancy test before taking part to exclude the possibility of pregnancy. Women who could become pregnant must use an effective contraceptive during the course of this study. Effective contraceptives include the pill, barrier methods (e.g. condoms), hormonal implants, contraceptive injections, intrauterine devices and sterilisation. Any woman who finds that she has become pregnant while taking part in the study should tell her research doctor immediately. Women of childbearing age who receive a transplant will usually find that their periods stop after the transplant and hormone replacement treatment will be given if indicated.**

### **Will my taking part in this study be kept confidential?**

Your general practitioner will be informed of your treatment with your permission. It may be necessary for your records to be inspected by regulatory bodies. All personal information which is collected about you during the course of the research will be kept strictly confidential and will not be seen by anyone not involved in the study. You will not be identified in any report or publication.

**For further information please contact:**

Dr Don Milligan on 0121 424 3699

or

Professor D Catovsky on 020 7808 2880

Given as an example: each hospital will provide the corresponding local information

Thank you for considering taking part in this study.