

Kansas City Clinical Oncology Program

CALGB C10001

A Phase II Trial of Sequential Chemotherapy, Imatinib Mesylate and Transplantation for Adults with Newly Diagnosed Ph+ Acute Lymphoblastic Leukemia by the CALGB and SWOG

Donor Consent Form

This is a clinical trial (a type of research study). Clinical trials include only patients who choose to take part. Please take your time to make your decision. Discuss it with your friends and family.

You have been identified as an “HLA-matched sibling,” that is a brother or sister who has the same genetic type of bone marrow cells and can therefore serve as a good donor of bone marrow or “stem cells.” During an “allogeneic” transplant, bone marrow or “stem cells” from a healthy donor are used for transplantation.

Why Is This Study Being Done?

You are being asked to take part in this study because you have a sibling that has been diagnosed with “Philadelphia chromosome positive” acute lymphoblastic leukemia (Ph+ ALL), a form of cancer that originates from the lymphocytes, the cells that make up the immune system and that are located in the bone marrow. Like some other forms of leukemia, Ph+ ALL is often difficult to treat with standard forms of treatment such as chemotherapy and radiation therapy.

A transplant of some of the sibling’s bone marrow or blood “stem cells” may be an effective treatment for Ph+ ALL. Stem cells are the original cells from which all the blood cells (including white blood cells which help fight infection, red blood cells that carry oxygen and platelets that help the blood to clot) develop. The use of high doses of chemotherapy to kill the leukemia cells followed by the intravenous transfusion of stem cells from a healthy sibling donor such as yourself, may improve the survival of patients with Ph+ ALL.

How Many People Will Take Part in the Study?

About 60 people will take part in the overall study, but we estimate that only 10-15 patients will have a “HLA-matched sibling” donor for the allogeneic transplant treatment.

What Is Involved in the Study?

Medical Tests

If you take part in this study, you will have blood tests to insure that you do not carry any communicable diseases that could be transmitted through your blood (such as hepatitis, HIV, etc.). Other tests to determine your suitability as a donor may be necessary, as well.

Treatment

It is possible to stimulate the bone marrow to produce stem cells with a drug called filgrastim, also known as G-CSF. G-CSF is a commercially available and approved medication used in patients receiving chemotherapy for cancer to increase the number of white blood cells, the cells responsible for fighting infections. When G-CSF is given to a healthy donor (that is, a brother or sister), it is possible to collect stem cells that can then be used to rescue their siblings who have cancer and are receiving high dose chemotherapy. The stem cells collected from the donor have immune effects that may also aid in recognizing and destroying any cancer cells that may still be in the patient's body after the high dose chemotherapy.

G-CSF will be given to you, the donor, for three to seven consecutive days as a daily injection just underneath the skin (subcutaneous injection). We will teach you or a family member to give you the injections at home. During the three to seven-day period in which you are receiving G-CSF, your white blood cell count will increase. After the third day, a process known as leukapheresis will be performed where the stem cells will be collected from your blood stream. A daily check of your blood counts will be performed on the days when you are undergoing leukapheresis. This requires approximately 5-10 mL of blood (equal to 1-2 teaspoons) to be removed by blood drawn from one of your veins.

The leukapheresis procedure is similar to the process of blood donation, where a needle is placed in the vein of the arm and blood is removed in a sterile fashion. In leukapheresis, this blood is removed in a continuous flow process and filtered using a sterile centrifuge so that only the white blood cells, stem cells, and some plasma are removed. About one-half pint of blood cells are collected for the transplant. The rest of the blood (mostly red blood cells and plasma) is returned back into your blood stream through a second needle. The leukapheresis procedures will be performed on the fourth day and, possibly, the fifth day after you have been receiving G-CSF. Each collection of stem cells will then be transfused directly into the patient (your brother or sister) who will have completed a course of irradiation and high dose chemotherapy.

How Long Will I Be in the Study?

We think you will be in the study for approximately 5-6 days. You may be asked to undergo additional leukaphereses in the first year after the treatment if additional treatments are needed for your brother or sister.

You can stop participating at any time. However, if you decide to stop participating in the study, we encourage you to talk to the researcher and your brother or sister's doctor first. There may be no consequences to your health if you discontinue participation in this study, but it may have serious affects on the recipient (that is, your brother or sister) if they have already received irradiation and chemotherapy for their transplant.

What Are the Risks of the Study?

A daily check of your blood counts will be performed on the days when you are undergoing leukapheresis. This will require approximately 5-10 mL of blood (equal to 1-2 teaspoons) to be removed by blood drawn from one of your veins. The risks of the blood draw include bruising, inflammation of the vein, and infection. Care will be taken to avoid these complications.

The most common side effect of G-CSF is bone pain as the bone marrow becomes active. This is not common but can be relieved with acetaminophen (Tylenol) in most cases. You should not take aspirin. Other rare side effects which have been described or reported include bruising at the injection sites, fever, nausea, vomiting, diarrhea, headache, skin rash, chest pain, hair loss, loss of appetite, shortness of breath, enlarged spleen, drop in blood pressure, and generalized weakness. All of these side effects go away when the G-CSF treatment is stopped. There are no known long-term side effects from the short-term use of G-CSF in normal donors.

The risks and side effects of the leukapheresis process have to do with the placement of the leukapheresis needles in the veins of the arms. These risks are similar to those involved in blood donation and include nausea, vomiting, dizziness, seizures (if you faint), blood loss, inflammation in the vein, and infection. Also, with the leukapheresis process, the platelet count (the cells partly responsible for blood clotting) may drop. This drop in blood counts is temporary and should return to normal within one or two days. The anticoagulant used to prevent your blood from clotting in the IV tubing can sometimes cause tingling in the fingertips and around the mouth. Extra calcium (for example, Tums) can prevent this side effect.

Risk of Testing for Infectious Illnesses: Participation in this study will require that you be tested for hepatitis and HIV. Testing for HIV and for the hepatitis viruses may result in a diagnosis of infection with these viruses. In the event that you are diagnosed with hepatitis or HIV, you may be referred to a doctor who specializes in these illnesses. The diagnosis of HIV or hepatitis may result in earlier treatment and/or prevention of many complications from the illnesses. Efforts will be made to keep your personal information confidential. Awareness of a diagnosis of these illnesses may have serious personal and social consequences. Some of these consequences include possible difficulty obtaining health insurance or employment.

For more information about risks and side effects, ask the researcher.

Are There Benefits to Taking Part in the Study?

Although there is no direct benefit to you, the donor, the stem cell transplant is potentially life saving to the recipient (your brother or sister) who is suffering from an otherwise fatal Ph+ acute lymphoblastic leukemia.

What Other Options Are There?

Your participation in this study is voluntary. You do not have to participate in this study.

What about Confidentiality?

Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law.

Organizations that may inspect and/or copy your research and medical records for quality assurance and data analysis include groups such as:

- Cancer and Leukemia Group B (CALGB)
- Southwest Oncology Group (SWOG)
- Kansas City Clinical Oncology Program (KCCOP)
- National Cancer Institute
- Food and Drug Administration
- Novartis (the makers of STI571, the agent that your brother or sister will receive as part of their treatment)

What Are the Costs?

The cost of the G-CSF medication and the leukapheresis procedure will be billed to you and your insurance company or your sibling's insurance company. Please ask about any expected added costs or insurance problems.

In the case of injury or illness resulting from this study, emergency medical treatment is available but will be provided at the usual charge. No funds have been set aside to compensate you in the event of injury.

You or your insurance company will be charged for continuing medical care and/or hospitalization.

You will receive no payment for taking part in this study.

What Are My Rights as a Participant?

Taking part in this study is voluntary. You may choose not to take part or may leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to which you are entitled.

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

Whom Do I Call if I Have Questions or Problems?

For questions about the study or a research-related injury, contact the researcher _____ *NAME(S)* at _____ *TELEPHONE NUMBER* .

For questions about your rights as a research participant, contact the KCCOP Institutional Review Board (which is a group of people who review the research to protect your rights) at (816) 823-0555.

Where Can I Get More Information?

You may call the NCI's Cancer Information Service at
1-800-4-CANCER (1-800-422-6237) or TTY: 1-800-332-8615

Visit the NCI's Web sites...

CancerTrials: comprehensive clinical trials information
http://www.cancer.gov/clinical_trials

CancerNet™: accurate cancer information including PDQ
http://www.cancer.gov/cancer_information

You will get a copy of this form. You may also request a copy of the protocol (full study plan).

Release

By signing this form you authorize KCCOP to access and obtain information that is required for the study. This may include your medical records, labs, radiologic films and reports and pathology specimens. This authorization to disclose your medical records shall not expire, even upon death, unless specifically revoked in writing by you.

Signature

I agree to take part in this study.

Participant _____ Date _____