What this study is about

This study compared two kinds of stem cell transplants and a newer drug for people with Philadelphia-positive acute lymphoblastic leukemia (ALL) along with cancer drug treatment (chemotherapy).

The official title of this study is: Alliance 10001 A phase II trial of sequential chemotherapy, imatinib mesylate (Gleevec, STI571) (NSC # 716051, IND #61135), and transplantation for adults with newly diagnosed Ph+ acute lymphoblastic leukemia by the CALGB and SWOG

Why the study was done

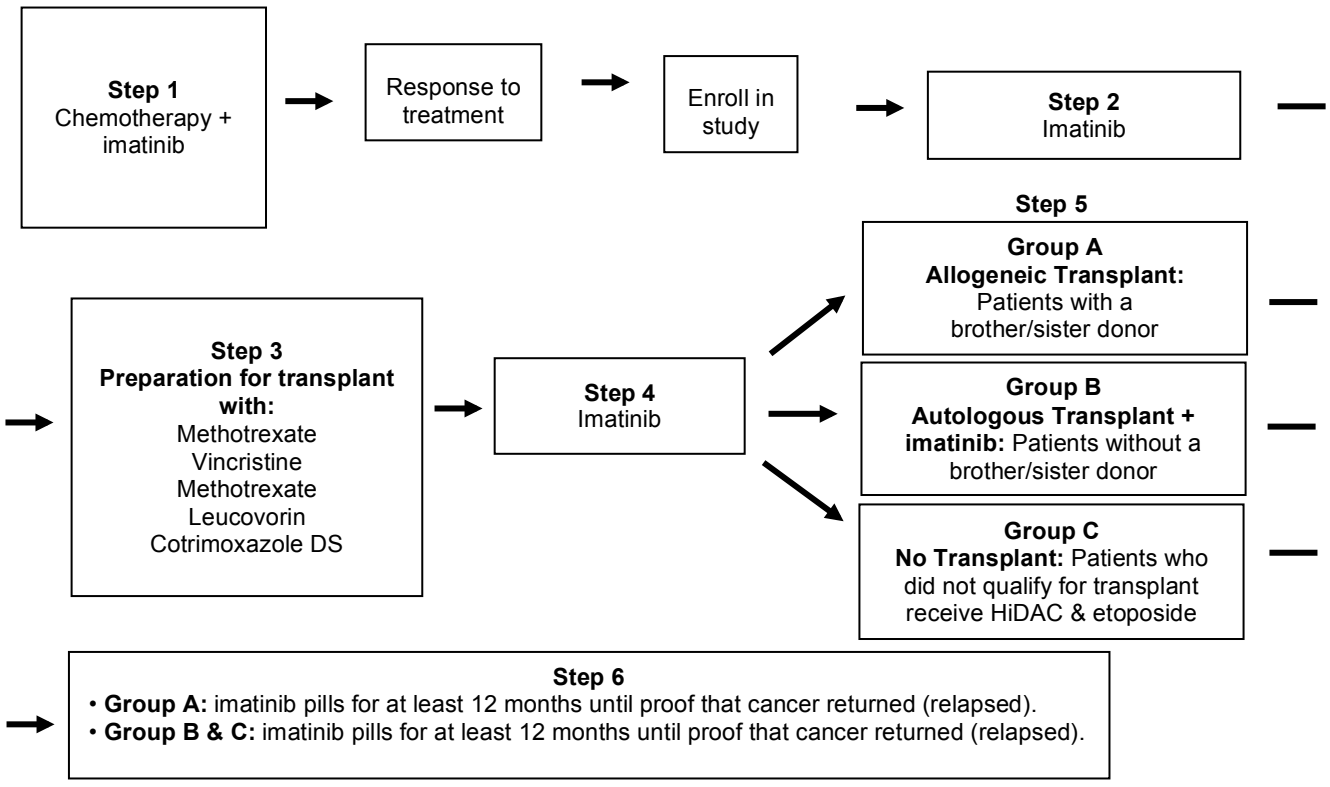
Acute lymphoblastic leukemia (ALL) is a cancer that grows in the bone marrow (inside bones), and makes too many cells called "lymphoblasts." Lymphoblasts are early blood cells (called "stem cells") that make different kinds of white blood cells. About 1 in 4 ALL patients (25%) have something called "Philadelphia Chromosome positive" ALL.

Normal treatment includes high doses of chemotherapy, followed by a transplant that replaces blood stem cells in the body. "Allogeneic" transplants use cells from a family member (like a brother or sister) to closely match the patient. Other transplants use a patient's own cells and are called "autologous" transplants. Allogeneic transplants are the most common because results are better as long as the body does not reject the outside cells, or the outside cells do not attack the patient's cells.

This study was done to see if autologous transplants were as effective as allogeneic transplants when the drug imatinib (Gleevec®) was added to the common treatment. Patients between 15 and 60 years old were included in this study.

All patients were given common chemotherapy with imatinib before the transplant. Patients who responded to this treatment were then put into these groups:
Group A: Patients with brother or sister donors were offered an allogeneic transplant.
Group B: Patients who did not have such a donor were offered an autologous transplant that used their own stem cells.
Group C: Patients who could not get a transplant for safety reasons. These patients received two drugs called "high-dose intermittent ARA-C" (called HiDAC) and etoposide.

Here is a picture that explains how patients were treated on the trial.



When did the study start and end? This study enrolled patients who joined between April 2002 and April 2010.

How many patients joined? 58 patients agreed to be in this study. 15 patients had an allogeneic transplant and 19 patients had an autologous transplant. The other patients left the study for many reasons.

Study results

Important findings:

- Patients in Group A and B had about the same amount of time before their cancers came back. This is called disease-free survival (DFS).
- Patients in Group A lived about as long as Group B. This is called overall survival (OS).
- Three of 15 patients (20%) in Group A died due to treatment, compared to 1 of 19 patients (5%) in Group B.

Other findings: Patients who agreed to be a part of this study had differences in their overall health when they first started the study, and before their transplant.

What the results mean

This means that patients who don't have a brother or sister to donate stem cells can still get the same results from an autologous transplant that uses their own cells.

These results are for patients with Philadelphia Chromosome-positive acute lymphoblastic leukemia (ALL) who are between 15 and 60 years old.

You can talk with your doctor for more information.

Scientific publications about this study

Details about the study can be found in these articles:

- Wetzler M, Watson D, Stock W, Koval G, Mulkey FA, Hoke EE, McCarty JM, Blum WG, Powell BL, Marcucci G, Bloomfield CD, Linker CA, Larson RA. Autologous transplantation for Philadelphia chromosome-positive acute lymphoblastic leukemia achieves outcomes similar to allogeneic transplantation - Results of CALGB Study 10001 (Alliance), Haematologica. 99(1):111-115, 2014

This sheet reviews what is known about this research study as of February 2014. New Information may be available.

This study was sponsored in part by Novartis US and by the Cancer and Leukemia Group B (CALGB), which is part of the Alliance for Clinical Trials in Oncology – a national cooperative network that runs large cancer clinical trials. The Alliance is supported by the National Cancer Institute (NCI) and brings researchers together to develop better treatments for cancers. More information about the Alliance is at http://www.allianceforclinicaltrialsinoncology.org.

To learn about this trial, visit the ClinicalTrials.gov website -- http://clinicaltrials.gov/ct2/show/study/NCT00039377?term=CALGB+10001&rank=1

Research studies (or clinical trials) are done to learn what treatments work better in people than what we already have. Thank you for your interest in learning more about cancer research advances.