What this study is about

This study compared different chemotherapy (drug) treatments to see if a drug called "fludarabine" raised the number of patients with chronic lymphocytic leukemia (CLL) who get a second kind of cancer.

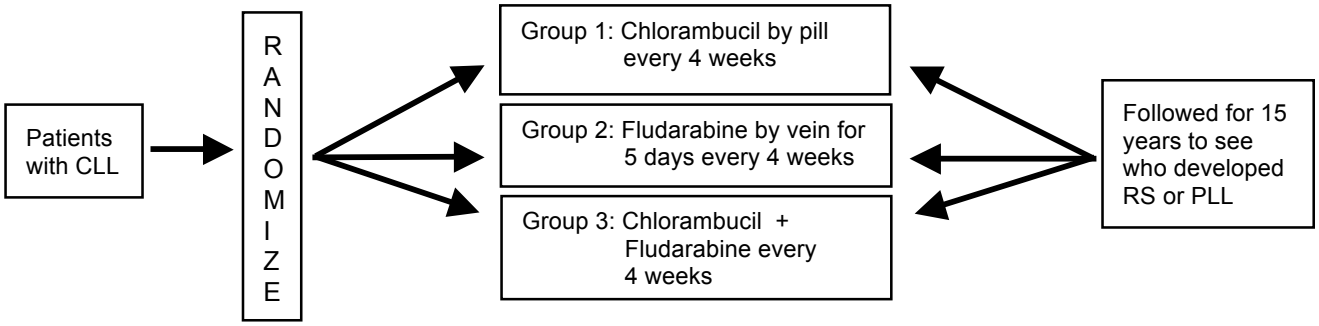
The official title of this study is: CALGB 9011 (Alliance)—A phase III comparison of fludarabine phosphate (NSC #312887) vs chlorambucil vs fludarabine phosphate + chlorambucil in previously untreated B-cell chronic lymphocytic leukemia

Why the study was done

Some people who are treated for chronic lymphocytic leukemia (CLL) develop a second kind of cancer at a later time. Second cancers can include one of two types. The first type is called "Richter Syndrome" (RS) and it can change into diffuse large cell lymphoma and other cancers. The second type is called "prolymphocytic leukemia" (PLL). It was thought that the drug called fludarabine (also called Fludara®), which is used to treat CLL, might raise the risk of getting these second cancers.

This study was done to see if patients with CLL who took fludarabine had an increased risk of either RS or PLL, when compared to patients who received other treatments for the CLL. Patients were followed for 15 years after they were enrolled in another treatment study that randomized them (assigned them by chance) into one of three groups either chlorambucil (called Leukeran®) only, fludarabine only, or both drugs together.

Here is a picture that explains how patients were placed into one of three treatment groups for their CLL:



When did the study start and end? This study reviewed what happened to patients who joined the treatment study between October 1990 and December 1994.

How many patients joined? 544 patients enrolled in the treatment study. 522 had records that could be followed for 15 years.

Study results

Important findings:

- 7 out of 100 patients (7%) got RS in about 22 months.
- 2 out of 100 patients (2%) got PLL.in about 15 months.
- There was no increase in RS or PLL in any of the treatment groups.

What the results mean

This means that fludarabine, when used to treat CLL, does not raise the risk of getting a second type of cancer such as the lymphoma or leukemia called RS or PLL compared to the other treatments that were tested.

These results are for patients with chronic lymphocytic leukemia (CLL).

You can talk with your doctor for more information.

Scientific publications about this study

Details about the study can be found in these articles:

- The impact of initial fludarabine therapy on transformation to Richter syndrome or prolymphocytic leukemia in patients with chronic lymphocytic leukemia: analysis of an intergroup trial (CALGB 9011)
  Aggarwal R, Halabi S, Kelly WK, et al.
  Leukemia & Lymphoma, 2013 Feb 54(2): 252-254

This sheet reviews what is known about this research study as of November 2013. New Information may be available.

This study was sponsored 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. For more information about the Alliance, visit http://www.allianceforclinicaltrialsinoncology.org

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.