Title

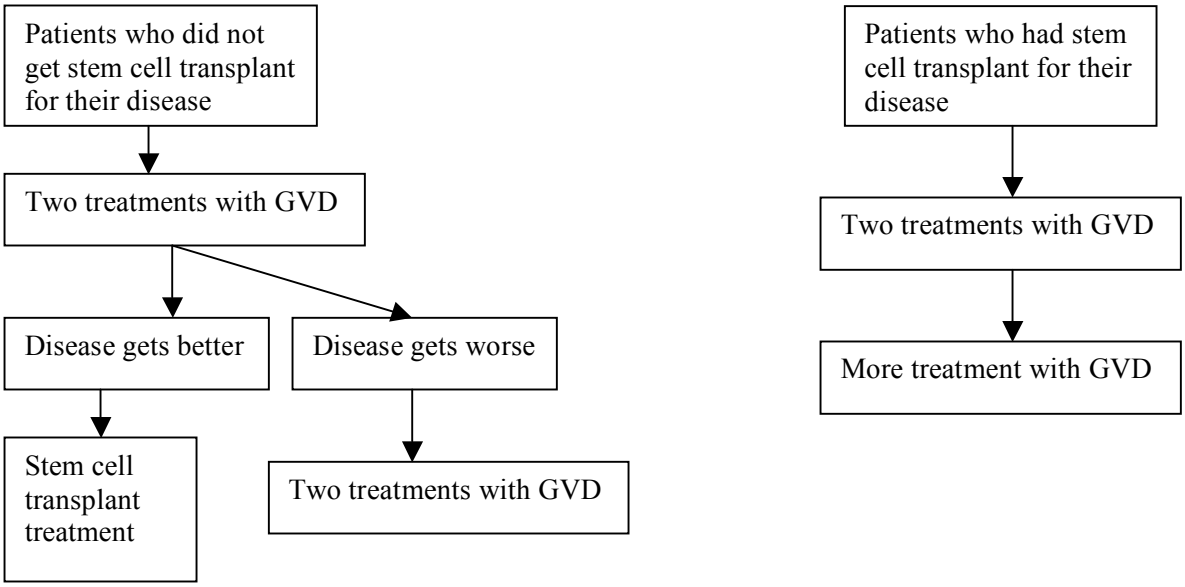
CALGB 59804—A phase I/II study of gemcitabine (Gemzar®)/ vinorelbine (Navelbine®)/liposomal doxorubicin (Doxil®) in relapsed/refractory Hodgkin's disease

Simple title: CALGB 59804: A Hodgkin's lymphoma study that examined a chemotherapy (drug) treatment to see if this treatment is effective and has tolerable side effects in patients whose disease had returned or had not responded to prior treatments.

Why the study was done

This study was done to help Hodgkin's lymphoma patients whose disease came back after treatment or had not responded to prior treatments. Usually, patients are treated with chemotherapy and then get a stem cell transplant if they can. Chemotherapy that is usually given can have bad side effects, especially in older patients. Studies have shown that there are three drugs with few side effects. These drugs are gemcitabine (G), vinorelbine (V) and liposomal doxorubicin (D). This study was done to see if combining these three drugs (the combination is called GVD) helps Hodgkin's lymphoma patients and is safe for patients. The patients participated in this study if they had one or more types of treatment for Hodgkin's lymphoma. Patients got lower amounts of chemotherapy if they were treated with stem cell transplant in the past. If the patients never had a stem cell transplant and responded to GVD treatment, they could have a stem cell transplant.

Here is a picture that explains how patients were placed into groups.



When did the study start and end? The study started in July 2000. All patients were enrolled by July 2003.

How many patients participated? 94 patients agreed to be in this study and 91 patients were treated. Of the 91 patients treated in this study, 51 never had stem cell transplants and 40 had prior transplants. Seventy-nine percent of patients had only one treatment before GVD, and 21 percent had more than one treatment before joining this study.

Study results

Important findings: Lymphoma improved in seven out of 10 (70 percent) of patients treated with GVD.

For the patients who had never had a stem cell transplant before this study:

- Seven out of 10 patients were still alive after four years.
- Eighty percent (39 out of 49) of patients went on to get a stem cell transplant, and 53 percent (26 out of 49) had no disease four years later.
- Half of the patients who were not able to get a stem cell transplant (five out of 10) were alive and had no disease four years later.

For the patients who had a stem cell transplant before this study:

- Patients lived an average of 3-1/2 years after treatment.
- For patients whose Hodgkin's lymphoma came back, it returned about 8-1/2 months after treatment.
- Side effects from GVD treatment were worse for this patient group than for those who had not had a previous stem cell transplant. Side effects included low blood counts and mouth sores.
- Most patients who died on this study died because their disease got worse rather than from side effects of the treatment.

What the results mean

GVD is a good treatment choice for patients with Hodgkin's lymphoma whose disease has returned after prior treatments or has not responded to prior treatments. Patients were able to tolerate the treatment well with fewer harmful side effects than seen with many usual chemotherapy treatments. Most patients treated with GVD were able to get a subsequent stem cell transplant for their Hodgkin's lymphoma.

When patients who had already had a stem cell transplant were treated with GVD, their disease got better. The disease usually came back though in 8-1/2 months. This suggests more studies need to be done to see if giving more GVD after stem cell transplant can keep patients' disease away longer.

This study applies to patients 18 years and older with Hodgkin's lymphoma that has returned after the initial treatment or has not responded to prior treatment.

Scientific publications about this study

Details about the study can be found in this article:

- Gemcitabine, vinorelbine and pegylated liposomal doxorubicin (GVD), a salvage regimen in relapsed Hodgkin's lymphoma: CALGB 59804
  Bartlett NL, Niedzwiecki D, Johnson LJ, Friedberg JW, Johnson KB, vanBesien K, Zelenetz AD, Cheson BD, Canellos GP for the Cancer and Leukemia Group B
  Annals of Oncology 18:1071-1079, 2007
- High expression of nucleoside transporter protein hENT1 in Reed-Sternberg cells is associated with treatment failure in relapsed/refractory Hodgkin lymphoma patients treated with gemcitabine, vinorelbine and liposomal doxorubicin – A CALGB 59804 correlative study
  Lai R, Bartlett NL, Mackey JR, Jung S, Johnson JL, Cook JR, Jones D, Cass CE, Young JD, Said J, Cheson B, Hsi ED
  Leukemia & Lymphoma 49(6): 1202-1205, 2008

This sheet reviews what is known about this research study as of March 2011. New Information may be available.

This study was sponsored by the Cancer and Leukemia Group B (CALGB) – a national cooperative group that conducts large-scale cancer clinical trials. The CALGB is supported by the National Cancer Institute (NCI) and brings together scientists to develop better treatments for cancer.

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.