Title

CALGB 60301—Pharmacokinetic and phase I study of sorafenib (BAY 43-9006, NSC 724772, IND #69896) for solid tumors and hematologic malignancies in patients with hepatic or renal dysfunction

Simple title: CALGB 60301: A study to find a safe dose of sorafenib (a cancer drug which is also called Nexavar®) for patients with cancer whose liver or kidneys are not working properly.

Why the study was done

Sorafenib (Nexavar®) is a pill used to treat some types of cancers, such as liver cancer and kidney cancer. The amount of the drug that can be taken safely may depend on how well the liver or kidneys are working.

The liver and the kidneys are organs in the body that help to support health in many ways, such as removing toxins from the blood. It is common in patients treated for cancer to have liver or kidney organs that do not work well. How well these organs work (function) can be revealed with blood tests.

Researchers wanted to find the safe dose of sorafenib to give to cancer patients with different levels of liver or kidney function, from normal to barely working.

The drug was given to groups of patients with a certain level of liver or kidney function at different doses for at least three weeks. If one dose was safe, the dose was increased in other patients with that level of liver or kidney function. If it was not safe, the dose was decreased in other patients with that level of liver or kidney function.

People who enrolled in the study had a liver and kidneys that worked (functioned) in these ways when they started on the study:

- **Normal function**
  - There were 12 patients who had normal **liver** and **kidney** function.
  - These patients got a 400 mg dose of sorafenib two times each day.
- **Mild loss of function**
  - There were 14 patients with mild **liver** problems and 18 patients with mild **kidney** problems.
- **Lower (moderate) function**
  - There were 21 patients with moderate **liver** problems and 14 patients with moderate **kidney** problems.
- **Severe loss of function**
  - There were 13 patients with severe **liver** problems and five patients with severe **kidney** problems.
- **Very severe loss of function**
  - There were 24 patients with very severe liver problems. There were 17 patients with **kidneys** that did not work, and they were on a machine that helped do the job kidneys normally do (called “dialysis”).

When did the study start and end? The study started in January 2005. All patients were enrolled by February 2007.

How many patients participated? 150 patients agreed to be in the study, and 138 actually took any drug.

Study results

Important findings: Patients whose liver or kidneys did not work at normal levels could not take the same dose of sorafenib that patients with normal function could take. The researchers were able to recommend safe doses for people with most, but not all, levels of liver and kidney function. This means the drug can be prescribed by physicians based on blood tests that show how well the liver or kidneys work.

What the results mean

Doctors who treat cancer can now use safer doses of sorafenib for many patients with less than normal liver or kidney function. Talk to your doctor for more information if you have this problem.

These results are for cancer patients 18 years and older who have less than normal liver or kidney function, and plan to take sorafenib. Most of the 138 patients in this study were White (106) or African-American (21).

Scientific publications about this study

Details about the study can be found in this article:
Phase I and pharmacokinetic study of sorafenib in patients with hepatic or renal dysfunction: CALGB 60301
Miller AA, Murry DJ, Owzar K, Hollis DR, Kennedy EB, Abou-Alfa G, Desai A, Hwang J, Villalona-Calero MA, Dees EC, Lewis LD, Fakih MG, Edelman MJ, Millard F, Frank RC, Hohl RJ, Ratain MJ
Journal of Clinical Oncology 27:1800-1805, 2009

You can also talk with your doctor for more information.

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; www.calgb.org) – a national cooperative group that runs 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 works better for people in order to find, treat, or prevent cancers. Thank you for your interest in learning more about cancer research advances.