Alliance Public Study Result Summary in Liver Cancer Study Number CALGB 80802

What this study is about

A cancer study that compared the effectiveness of sorafenib plus doxorubicin to sorafenib alone for the treatment of advanced hepatocellular carcinoma (HCC), commonly known as liver cancer.

The full title of this study is: Phase III Randomized Study of Sorafenib Plus Doxorubicin Versus Sorafenib in Patients with Advanced Hepatocellular Carcinoma (HCC)

Why the study was done

This study was done to see if sorafenib plus doxorubicin was better than sorafenib alone for the treatment of advanced HCC.

Study results

These results are for people with locally advanced or metastatic HCC.

The study found that adding doxorubicin to sorafenib did not work better than sorafenib alone in treating patients with advanced HCC.

The most common serious side effects included:

Doxorubicin and Sorafenib

- 13 out of every 100 patients (13%) had fatigue
- 13 out of every 100 patients (13%) had hand-foot skin reactions
- 37 out of every 100 patients (37%) had blood related issues
- 24 out of every 100 patients (24%) had decreased platelet counts

Sorafenib

- 10 out of every 100 patients (10%) had fatigue
- 14 out of every 100 patients (14%) had hypertension (high blood pressure)
- 14 out of every 100 patients (14%) had hand-foot skin reactions

What the results mean

This study was stopped earlier than expected. There were no significant differences between the two study groups.

These results were not expected since the drug combination of sorafenib plus doxorubicin showed promise in early studies.

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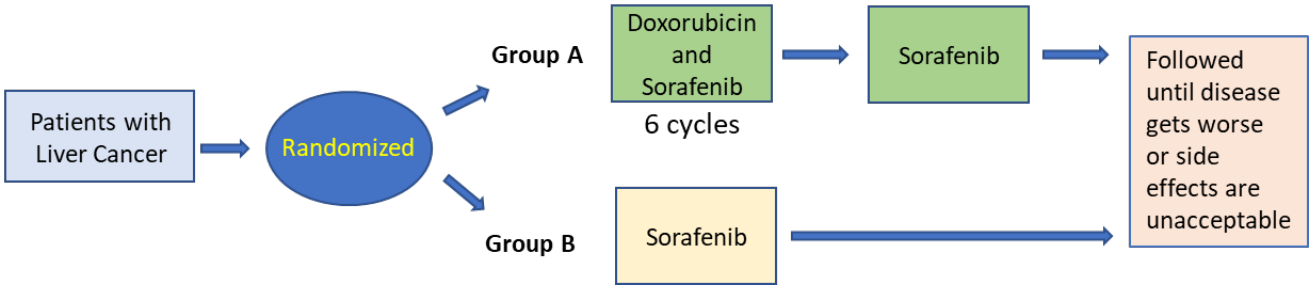
How the study worked

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



Randomization is the process by which patients are assigned by chance to separate groups.
Doxorubicin and Sorafenib Group A – 60 mg of doxorubicin in a vein every 21 days for a maximum dose of 360 mg plus 400 mg of sorafenib by mouth two times daily for 6 three week cycles followed by sorafenib alone.
Sorafenib Group B – 400 mg of sorafenib by mouth two times daily.

Patients were randomized to Arm A or Arm B. Patients on Arm A took sorafenib by mouth with a glass of water twice a day without food. They also received doxorubicin through a needle in the vein once every 3 weeks for 6 cycles (18 weeks). Patients continued taking sorafenib until their disease got worse or the side effects were unacceptable. Patents in Arm B took sorafenib by mouth with a glass of water twice a day without food until their disease got worse or the side effects were unacceptable.

When did the study start and end? The study started in February 2010. Enrollment was stopped in May 2015.

How many patients joined? Originally, the study planned on enrolling 480 patients, but only 356 enrolled because the study ended early.

Talk to your doctor if you want more information about this study.

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Scientific publications about this study

Details about the study can be found in these articles:

- Abou-Alfa GK, Shi Q, Knox JJ, Kaubisch A, Niedzwiecki D, Posey J, Tan BR Jr, Kavan P, Goel R, Lammers PE, Bekaii-Saab TS, Tam VC, Rajdev L, Kelley RK, El Dika I, Zemla T, Potaracke RI, Balletti J, El-Khoueiry AB, Harding JH, Suga JM, Schwartz LH, Goldberg RM, Bertagnolli MM, Meyerhardt J, O'Reilly EM, Venook AP. Assessment of Treatment With Sorafenib Plus Doxorubicin vs Sorafenib Alone in Patients With Advanced Hepatocellular Carcinoma: Phase 3 CALGB 80802 Randomized Clinical Trial. JAMA Oncol. 2019 Sep 5;5(11):1582–8. doi: 10.1001/jamaoncol.2019.2792. Epub ahead of print. Erratum in: JAMA Oncol. 2019 Oct 10;: PMID: 31486832; PMCID: PMC6735405.

To learn about this trial, visit the ClinicalTrials.gov website at:
https://clinicaltrials.gov/ct2/show/NCT01015833

This study was sponsored by the Alliance for Clinical Trials in Oncology – a national clinical trial network group 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 www.AllianceNCTN.org.

This summary lists what is known about this research study as of July 2021.

We thank the people who joined this study and made it possible.
We do research to try to learn the best ways to help patients.
The people who joined this study helped us to do that.

Thank you for your interest in learning more about cancer research advances.