Alliance Public Study Result Summary
CALGB 80405

What this study is about

A cancer study that compared different chemotherapy (drug) treatments for adults with colon or rectal cancer that has returned or spread throughout the body.

The full title of this study is: A phase III trial of irinotecan / 5-FU / leucovorin or oxaliplatin / 5-FU/ leucovorin with bevacizumab, or cetuximab (c225), or with the combination of bevacizumab and cetuximab for patients with untreated metastatic adenocarcinoma of the colon or rectum

Why the study was done

Past studies showed that adding drugs that could either suppress blood vessel growth (bevacizumab) or block tumor cell growth signals (cetuximab) could increase survival time beyond that seen with standard chemotherapy alone. This study was done to see which of these agents was most able to increase survival when added to standard chemotherapy (either FOLFOX6 or FOLFIRI) for people with colon or rectal cancer that has returned or spread throughout the body. The study also tested whether adding both agents to standard chemotherapy was better than adding either alone.

Study results

These results are for people with colon or rectal cancer that has spread to organs such as the lungs or liver, or has grown in ways that make it impossible to be completely removed by surgery. These results are also specific to people whose cancer has not already been treated with chemotherapy, and also whose cancer does not show one of a particular set of mutations in the K-ras gene.

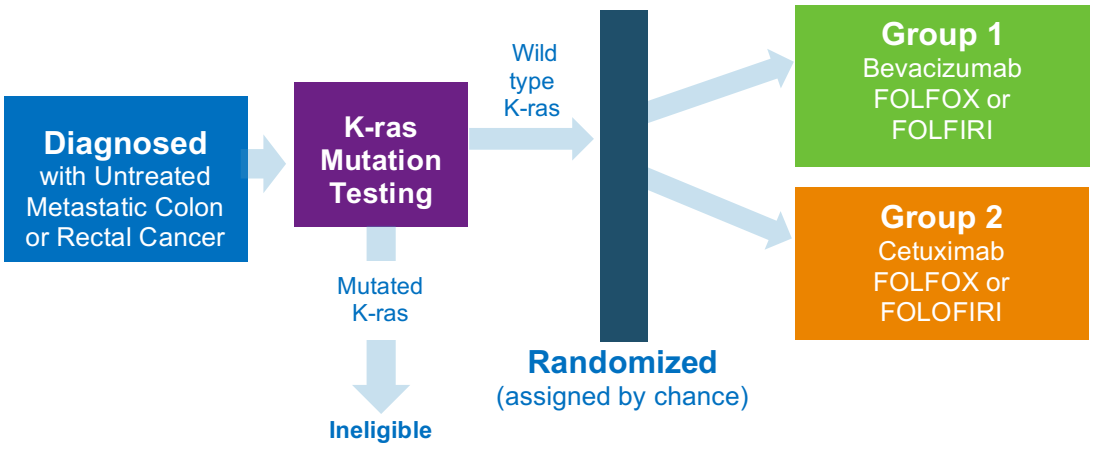
When both bevacizumab and cetuximab were added together to standard chemotherapy in other studies, there was no better survival compared to either drug alone, and the side effects were worse, and so this part of the study was stopped after only a few people were treated. This large study of 1137 patients found that half of patients treated with chemotherapy (either FOLFOX6 or FOLFIRI) plus cetuximab were living 30 months or more after beginning treatment, and half of all patients treated with chemotherapy plus bevacizumab were living 29 months or more after beginning treatment.

What the results mean

This means that either cetuximab or bevacizumab can be added to standard chemotherapy for people with colon or rectal cancer that has returned or spread throughout the body and has one of a set of mutations in the K-ras gene.

How the study worked

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



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When did the study start and end? The study started in November 2005. All patients were enrolled by March 2012.

How many patients joined? 1,137 patients participated in this study

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

Scientific publications about this study

This summary includes information in the following article:

- **Effect of First-Line Chemotherapy Combined with Cetuximab or Bevacizumab on Overall Survival in Patients with KRAS Wild-Type Advanced or Metastatic Colorectal Cancer: A Randomized Clinical Trial.** Venook AP, Niedzwiecki D, Lenz HJ, Innocenti F, Fruth B, Meyerhardt JA, Schrag D, Greene C, O'Neil BH, Atkins JN, Berry S, Polite BN, O'Reilly EM, Goldberg RM, Hochster HS, Schilsky RL, Bertagnolli MM, El-Khoueiry AB, Watson P, Benson AB 3rd, Mulkerin DL, Mayer RJ, Blanke C. JAMA. 2017 Jun 20;317(23):2392-2401. doi: 10.1001/jama.2017.7105.

Other details about the study can be found in these articles:

- **Revisiting the Cancer and Leukemia Group B/Southwest Oncology Group 80405 Trial: A Phase III Trial of Chemotherapy and Biologic Agents for Patients with Untreated Advanced Colorectal Adenocarcinoma.** Venook AP, Blanke CD, Niedzwiecki D, Lenz HJ, Taylor JR, Hollis DR, Sutherland S, Goldberg RM. Clin Colorectal Cancer. 2007 May;6(7):536-8.

- **Cancer and Leukemia Group B/Southwest Oncology Group trial 80405: A Phase III Trial of Chemotherapy and Biologics for Patients with Untreated Advanced Colorectal Adenocarcinoma.** Venook AP, Blanke CD, Niedzwiecki D, Lenz HJ, Taylor JR, Hollis DR, Sutherland S, Goldberg RM. Clin Colorectal Cancer. 2005 Nov;5(4):292-4.

To learn about this trial, visit the ClinicalTrials.gov website at
https://clinicaltrials.gov/ct2/show/results/NCT00265850

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 http://www.allianceforclinicaltrialsinoncology.org.

This summary lists what is known about this research study as of June 2017.
New Information may be available.

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.