Alliance Public Study Result Summary
CALGB 80403

What this study is about

A study that compared different drug (chemotherapy) treatments for patients with esophageal cancer or gastroesophageal junction cancer that has spread to other places in the body.

The full title of this study is: Randomized phase II study of ECF-C, IC-C, or FOLFOX-C in metastatic esophageal and gastroesophageal junction cancer.

Why the study was done

This study was done to see which first chemotherapy treatment had more cancer tumors shrink in patients with cancer in the esophagus and other parts of their bodies. This study also included patients who had cancer on the area between the esophagus and stomach.

Usual treatments don't work as well as doctors and patients would like, with only about 4 out of 10 cancer tumors (42% to 45%) responded, and about 1 in 2 patients (50%) lived less than one year. Other studies showed that a drug that was approved for other diseases might help make the usual treatments work better. This other drug is called cetuximab (common brand name erbitux).

Study results

These results are for people with esophagus cancer that spread to other parts of the body. This is called metastatic cancer or stage IV. Patients on this study received one of three different chemotherapy treatments.

This study found that the usual chemotherapy treatments in Group 1 (ECF) and Group 3 (FOLFOX) shrunk more cancer tumors than treatment in Group 2 (IC).

Patients in Group 3 who took FOLFOX had fewer side effects. Patients on FOLFOX were able to better finish their treatment without having to lower the dose or stop their chemotherapy. Patients in Group 2 who took IC had more stomach problems as a side effect than those in Group 1 or 3.

About 1 in 3 patients (33%) had a drop in their blood counts, no matter which group they were in. This drop can lower the immune systems, causing more infections. It can also make blood thinner and carry less oxygen through the body.

What the results mean

This means FOLFOX chemotherapy with cetuximab helped shrink more tumors for a longer period of time. Patients on FOLFOX also had fewer side effects.

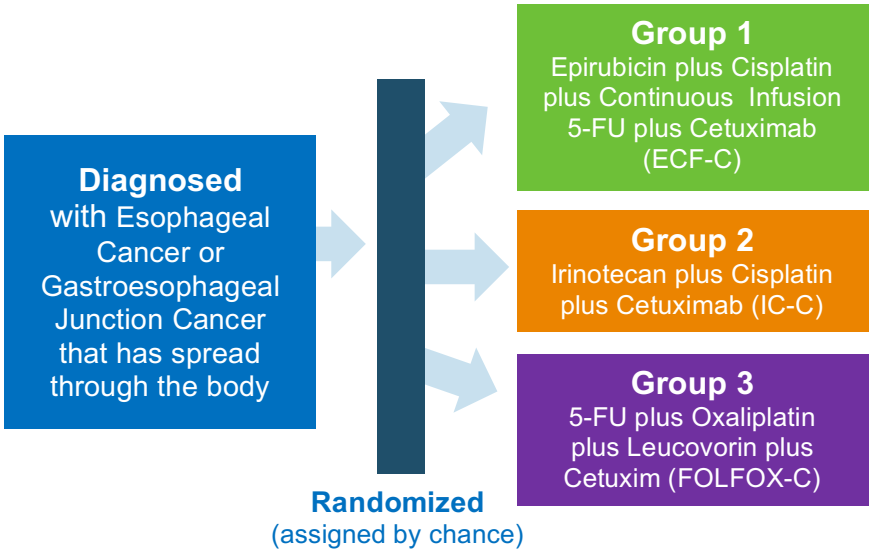
How the study worked

Patients were assigned by chance (randomized) to one of three groups. This made sure that each patient had the same chance of being in any study group. All patients received treatment, and all groups got cetuximab to see if it helped one usual treatment more than the other usual treatments. This was the first treatment these patients had for this diagnosis. All drugs were given by vein in the office.

- Group 1 got the usual treatment that included drugs called epirubicin (common brand names ellence, pharmorubicin, PFS), cisplatin (common brand names platinol, platinol-AQ), and 5-FU (common brand name Adrucil), along with cetuximab. This was called ECF-C. They could also choose another usual treatment of 5-FU with cetuximab.
- Group 2 got a usual treatment called IC that included irinotecan (common brand name Camptosar) and cisplatin, plus cetuximab.
- Group 3 got a usual treatment called FOLFOX that included 5-FU, oxaliplatin (common brand name eloxatin) and leukovorin (common brand name wellcovorin), plus cetuximab.

Alliance Public Study Result Summary
CALGB 80403

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



When did the study start and end? The study started in September 2006. All patients were enrolled by May 2009.

How many patients joined? 245 patients were enrolled in this study. Group 1 had 82 patients; Group 2 had 83 patients; and Group 3 had 80 patients. More than 8 in 10 patients (88%) were men.

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:

- **CALGB 80403 (Alliance)/E1206: A Randomized Phase II Study of Three Chemotherapy Regimens Plus Cetuximab in Metastatic Esophageal and Gastroesophageal Junction Cancers.** Enzinger PC, Burtness BA, Niedzwiecki D, Ye X, Douglas K, Ilson DH, Villaflor VM, Cohen SJ, Mayer RJ, Venook A, Benson AB 3rd, Goldberg RM. J Clin Oncol. 2016 Aug 10;34(23):2736-42. doi: 10.1200/JCO.2015.65.5092. Epub 2016 Jul 5.

To learn about this trial, visit the ClinicalTrials.gov website at
https://clinicaltrials.gov/ct2/show/NCT00381706

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 July 2016.
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.