Alliance Public Study Result Summary
Alliance A021101

What this study is about

A pilot study that compared different chemotherapy (drug) treatments before surgery for adults with pancreatic cancer.

The full title of this study is: Neoadjuvant FOLFIRINOX and chemoradiation followed by definitive surgery and postoperative gemcitabine for patients with borderline resectable pancreatic adenocarcinoma: An intergroup single-arm, pilot study

Why the study was done

This study was done to see if chemotherapy can make surgery more successful in people with pancreatic cancer that has not spread throughout the body, but is still very difficult to remove by surgery because it is either large, involves important blood vessels or other nearby structures.

Study results

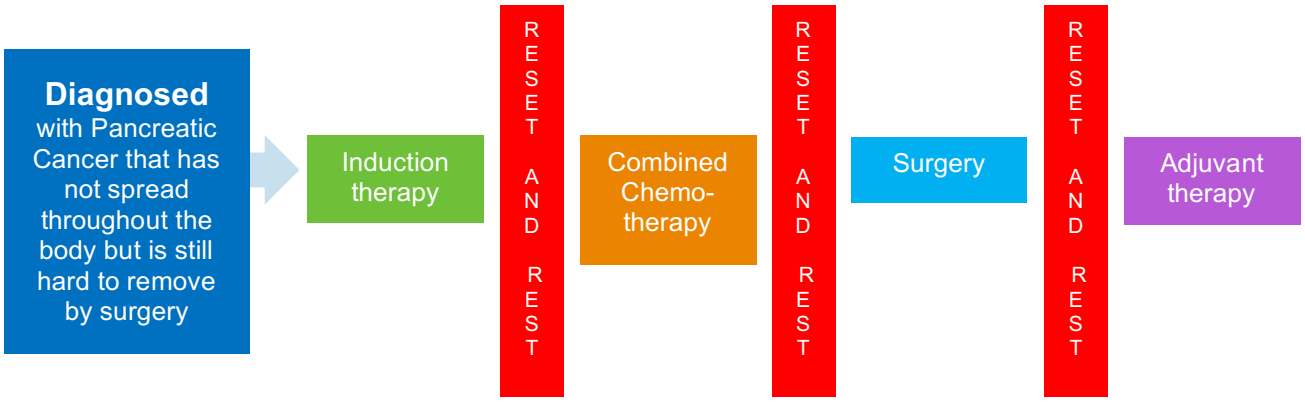
These results are for people with pancreatic cancer that has not spread throughout the body, but is very difficult to remove by surgery because it is either large, involves important blood vessels or other nearby structures. In this case, which is known as borderline resectable pancreas cancer, it is sometimes possible to make surgery possible by shrinking the cancer using chemotherapy and radiation. Chemotherapy and radiation can, in some cases, cause severe side effects, and we do not know if this approach benefits patients by increasing survival time or improving quality of life. In this study, 22 patients with borderline resectable pancreas cancer were treated with a combination of chemotherapy and radiation. The study showed that, following this treatment, 15 of the 22 patients, or 68%, were able to have surgery that removed all visible tumor. Also, about half of the tumors removed during surgery showed high levels of tumor cell destruction when examined microscopically.

What the results mean

This means that chemotherapy and radiation given to people with borderline resectable pancreas cancer can lead to successful removal of the visible tumor in about 2.3 of the cases. This therapy should be studied further to find out if it increases length of survival or improves quality of life in patients with borderline resectable pancreas cancer.

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 May 2013. All patients were enrolled by August 2014.

How many patients joined? 23 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:

- **Preoperative Modified FOLFIRINOX Treatment Followed by Capecitabine-Based Chemoradiation for Borderline Resectable Pancreatic Cancer: Alliance for Clinical Trials in Oncology Trial A021101.** Katz MH, Shi Q, Ahmad SA, Herman JM, Marsh Rde W, Collisson E, Schwartz L, Frankel W, Martin R, Conway W, Truty M, Kindler H, Lowy AM, Bekaii-Saab T, Philip P, Talamonti M, Cardin D, LoConte N, Shen P, Hoffman JP, Venook AP. JAMA Surg. 2016 Aug 17;151(8):e161137. doi: 10.1001/jamasurg.2016.1137. Epub 2016 Aug 17

To learn about this trial, visit the ClinicalTrials.gov website at
https://clinicaltrials.gov/ct2/show/NCT01821612

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 August 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.