Alliance Public Study Result Summary
ACOSOG Z6051

What this study is about

A study that compared two types of surgery currently used in rectal cancer.

The full title of this study is: A phase III prospective randomized trial comparing laparoscopic-assisted resection versus open resection for rectal cancer

Why the study was done

It is possible to remove cancer of the rectum using very small incisions with the help of special cameras and instruments. This approach is known as laparoscopic surgery, and it is possible that this method may allow people to recover faster from surgery and with less pain. To treat rectal cancer, it is very important that all tumor cells are completely removed with a rim of normal tissue surrounding the tumor. This is known as a "negative margin" and is a very important factor in determining whether or not the cancer will return after surgery.

This study was done to see if laparoscopic surgery for rectal cancer could be just as good as standard surgery with larger incisions when it comes to removing the entire cancer with a negative margin.

Study results

These results are for people with rectal cancer that has not spread throughout the body and does not involve organs other than the rectum.

The study found that a negative margin was achieved in 92.3% of patients whose surgery used a standard incision and 87.9% of patients how had laparoscopic surgery. Laparoscopic surgery took an average of about 45 minutes longer than standard surgery, and was the same compared to the standard incision for time spent in the hospital and chance of severe complications after surgery.

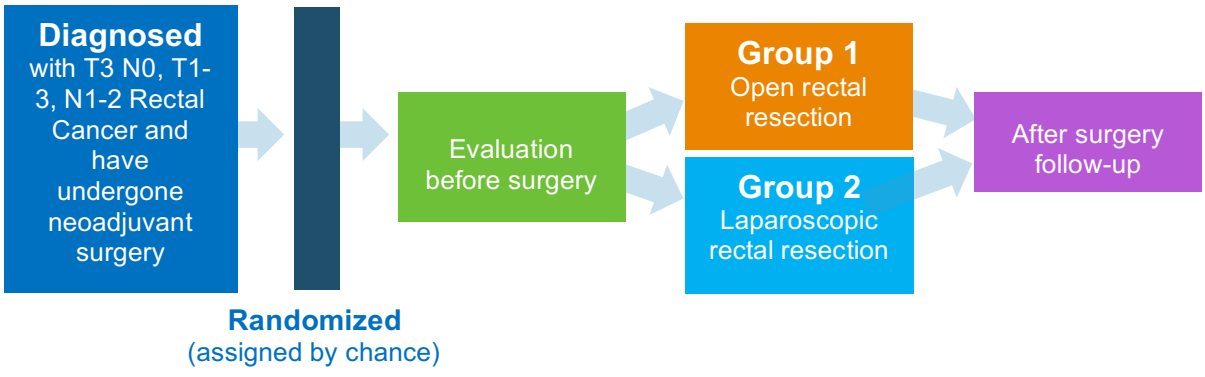
What the results mean

This means that laparoscopic surgery for rectal cancer may not be better than surgery using a standard larger incision when it comes to the very important issue of completely removing the tumor with a negative margin. The study is still gathering information to see if the chance for cancer cure is different between the two types of surgery.

How the study worked

Patients in this study were assigned by chance (randomized) to one of two groups. This made sure that each patient had the same chance of being in any study group.

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 October 2008. All patients were enrolled by September 2013.

How many patients joined? 486 patients agreed to be 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 Laparoscopic-Assisted Resection vs Open Resection of Stage II or III Rectal Cancer on Pathologic Outcomes: The ACOSOG Z6051 Randomized Clinical Trial.** Fleshman J, Branda M, Sargent DJ, Boller AM, George V, Abbas M, Peters WR Jr, Maun D, Chang G, Herline A, Fichera A, Mutch M, Wexner S, Whiteford M, Marks J, Birnbaum E, Margolin D, Larson D, Marcello P, Posner M, Read T, Monson J, Wren SM, Pisters PW, Nelson H. JAMA. 2015 Oct 6;314(13):1346-55. doi: 10.1001/jama.2015.10529.

To learn about this trial, visit the ClinicalTrials.gov website at
https://clinicaltrials.gov/ct2/show/NCT00726622

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 October 2015.
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.