Alliance Public Study Result Summary in pancreatic cancer Study Number A021501

What this study is about

A cancer study that looked at both chemotherapy alone and chemotherapy followed by radiation therapy before pancreatic cancer surgery.

The full title of this study is: Preoperative Extended Chemotherapy vs. Chemotherapy Plus Hypofractionated Radiation Therapy for Borderline Resectable Adenocarcinoma of the Head of the Pancreas

Why this study was done

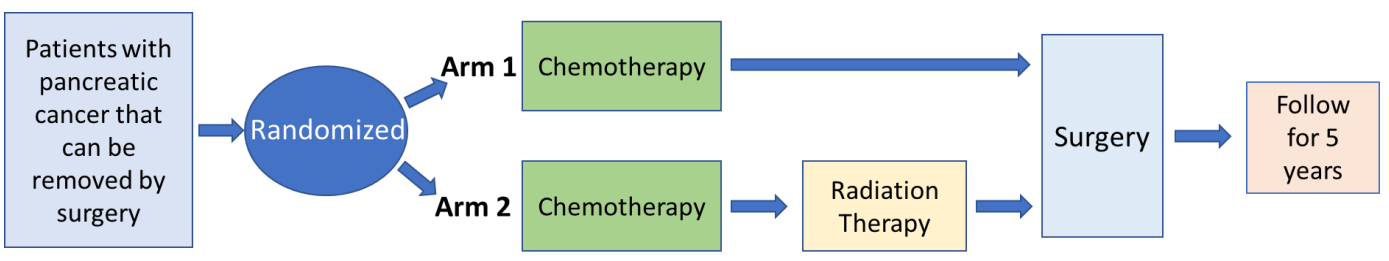
This study looked at how well chemotherapy alone or chemotherapy followed by radiation therapy worked. These treatments were given to patients with pancreatic cancer before a planned surgery.

Chemotherapy works in different ways to stop the growth of tumor cells. It can either kill the cancer cells, by stopping them from dividing, or by stopping them from spreading. Hypofractionated radiation therapy is when high doses of radiation therapy are given over a short period of time. Giving radiation therapy this way may kill more tumor cells and have fewer side effects.

It was not known if chemotherapy is more effective with or without hypofractionated radiation therapy when given before surgery.

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.
Chemotherapy: 7 cycles (1 cycle is 2 weeks) of modified FOLFIRINOX; oxaliplatin; irinotecan; leucovorin and fluorouracil given through the vein before surgery.
Radiation Therapy: Given daily for 1 week after chemotherapy (Arm 2 only)

Patients with pancreatic cancer that can be removed by surgery were randomly assigned to receive chemotherapy (Arm 1) or chemotherapy followed by radiation therapy (Arm 2). Patients were assigned to receive surgery and then followed for 5 years.

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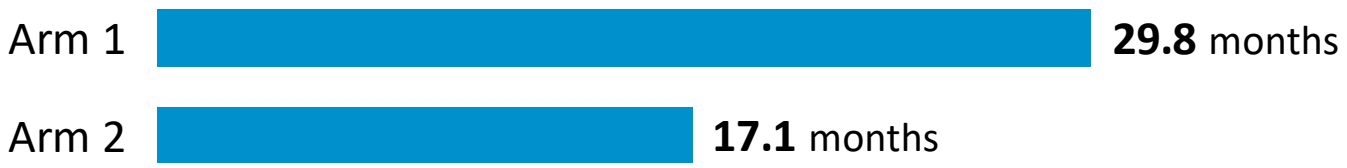
Study Results

These results are for people with pancreatic cancer that can be removed by surgery.

The study found that patients treated with chemotherapy alone (Arm 1) before surgery lived longer than patients treated with chemotherapy followed by radiation therapy (Arm 2). Furthermore, patients who received chemotherapy lived longer than was estimated based on data from older studies.

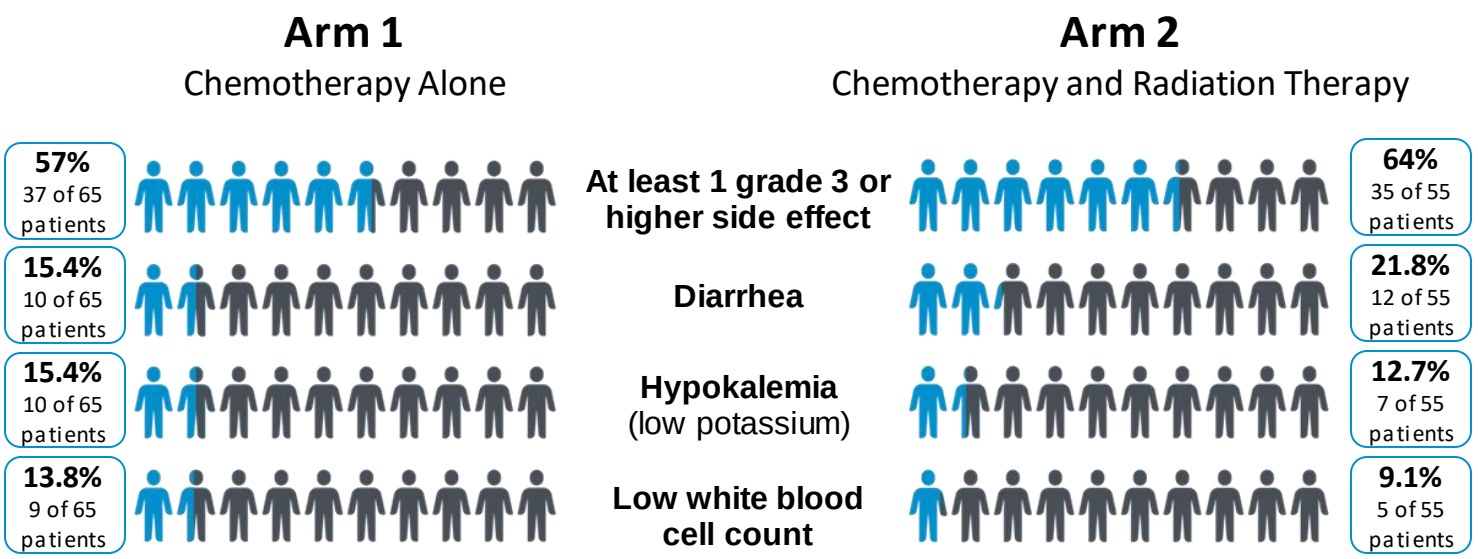
Median Survival



Median Survival means half of people did better (lived more months) than the months indicated above. Half of people did worse (lived fewer months).

Side Effects

The most common serious side effects (more than 10 out of every 100 patients) included:



What the results mean

This means that in patients with pancreatic cancer that can be removed by surgery, chemotherapy (mFOLFIRINOX) may be a better option than chemotherapy followed by radiation therapy for most patients.

The study leaves open the possibility that radiation therapy may benefit some patients. More studies are needed.

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When did the study start and end? The study started in December 2016. All patients were enrolled by August 2018.

How many patients joined? 126 patients agreed to be in this study. 120 patients completed the study.

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

Scientific Publications

Details about the study can be found in these articles:

- Katz MHG, Shi Q, Meyers J, Herman JM, Chuong M, Wolpin BM, Ahmad S, Marsh R, Schwartz L, Behr S, Frankel WL, Collisson E, Leenstra J, Williams TM, Vaccaro G, Venook A, Meyerhardt JA, O'Reilly EM. Efficacy of Preoperative mFOLFIRINOX vs mFOLFIRINOX Plus Hypofractionated Radiotherapy for Borderline Resectable Adenocarcinoma of the Pancreas: The A021501 Phase 2 Randomized Clinical Trial. JAMA Oncol. 2022 Jul 14. doi: 10.1001/jamaoncol.2022.2319. [Epub ahead of print]

To learn about this trial, visit the ClinicalTrials.gov website at: https://clinicaltrials.gov/ct2/show/NCT02839343

About the Alliance for Clinical Trials in Oncology

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.allianceforclinicaltrialsinoncology.org.

Thank you

This summary lists what is known about this research study as of September 2022.

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 advances in cancer research.