Alliance Public Study Result Summary
Study Number CALGB 31102

What this study is about

A cancer study that determined if it was safe to give radiation therapy over shorter lengths of time for patients with locally advanced (stage 3) lung cancer. They looked at how much radiation therapy could safely be given each day with chemotherapy.

The full title of this study is: Phase I Study of Accelerated Hypofractionated Radiation Therapy with Concomitant Chemotherapy for Unresectable Stage III Non-Small Cell Lung Cancer

Why the study was done

This study was done to see if it is safe and effective to give the same total dose of radiation therapy over a shorter period of time with chemotherapy. This means higher than usual doses of radiation therapy were given each day.

Study results

These results are for people with stage 3 non-small cell lung cancer that cannot be removed by surgery.

The study found that:

- The shortest amount of time to safely give radiation therapy was 24 treatments given once daily over 5 weeks.
- This is fewer treatments compared to usual treatment given in 30 treatments over 6 weeks.

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

Group 1 (there were 6 patients in this group)

- 16 out of every 100 patients (16%) had lung infections

Group 2 (there were 6 patients in this group)

- 16 out of every 100 patients (16%) had fatigue
- 16 out of every 100 patients (16%) died from hemoptysis (coughing up blood)

Group 3 (there were 6 patients in this group)

- 20 out of every 100 patients (20%) died from hemoptysis (coughing up blood)
- 20 out of every 100 patients (20%) died from pneumonitis, pulmonary infiltrations (inflammation and substances in the lungs)

Group 4 (there were 3 patients in this group)

- 33 out of every 100 patients (33%) had lung infections
- 33 out of every 100 patients (33%) had dry skin

What the results mean

This means:

- It may be possible to give radiation therapy in fewer treatments over a shorter period of time.
- Further studies are needed to determine whether this improves survival while remaining safe.

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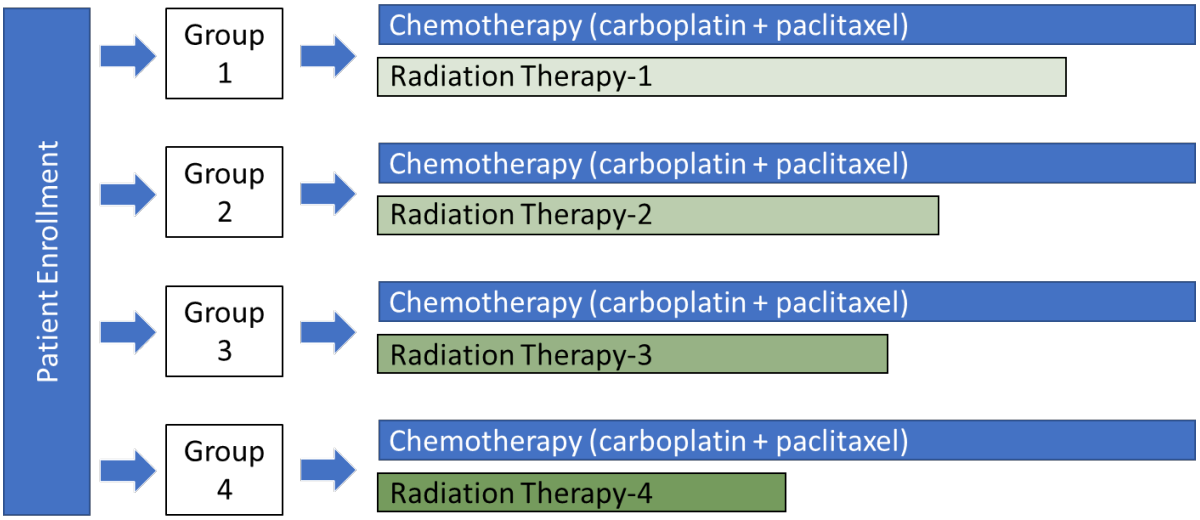
How the study worked

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



Chemotherapy was given the same way for each group. Carboplatin and paclitaxel were given weekly for the first 4 weeks followed by every 3 weeks. Radiation therapy was given during the first 3 cycles of chemotherapy.
In Group 1 **Radiation Therapy-1** was given at a dose of 2.22 Gy each day for 27 treatments over 5.5 weeks.
In Group 2 **Radiation Therapy-2** was given at a dose of 2.50 Gy each day for 24 treatments over 5 weeks.
In Group 3 **Radiation Therapy-3** was given at a dose of 2.73 Gy each day for 22 treatments over 4.5 weeks.
In Group 4 **Radiation Therapy-4** was given at a dose of 3.00 Gy each day for 20 treatments over 4 weeks.

Patients were assigned to a group based on when they joined the study. Initial patients were assigned to group 1. Once safety was determined in group 1, the next patients were assigned to group 2. This continued until group 4 was filled.

When did the study start and end? The study started in July 2012. All patients were enrolled by May 2014.

How many patients joined? 22 patients agreed to be in this study and 21 patients completed the study.

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

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Scientific publications about this study

Details about the study can be found in these articles:

- Urbanic JJ, Wang X, Bogart JA, Stinchcombe TE, Hodgson L, Schild SE, Bazhenova L, Hahn O, Salgia R, Vokes EE. Phase 1 Study of Accelerated Hypofractionated Radiation Therapy With Concurrent Chemotherapy for Stage III Non-Small Cell Lung Cancer: CALGB 31102 (Alliance). Int J Radiat Oncol Biol Phys. 2018 May 1;101(1):177-185. doi: 10.1016/j.ijrobp.2018.01.046. Epub 2018 Jan 31. PMID: 29487024; PMCID: PMC6173195.

To learn about this trial, visit the ClinicalTrials.gov website at https://www.clinicaltrials.gov/ct2/show/NCT01486602

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.AllianceNCTN.org.

This summary lists what is known about this research study as of November 2020.

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.