ECOG-ACRIN
cancer research group

EA5142/ANVIL Clinical Trial Results Summary

Testing the Addition of the Drug Nivolumab after Surgery for Non-small Cell Lung Cancer

What did this trial involve and who was it for?

EA5142, also known as Adjuvant Nivolumab in Resected Lung Cancer (ANVIL), was for people with stage 1B-3A non-small cell lung cancer (NSCLC) who had surgery to remove the cancer and then received chemotherapy and/or radiation therapy. The purpose of the trial was to learn whether adding nivolumab, an immunotherapy drug that activates your body's own immune system to attack cancer cells, would help patients live longer without their NSCLC returning. At the time of the trial, nivolumab was already approved by the Food and Drug Administration (FDA) for more advanced NSCLC that had spread beyond the lung, but it was not yet approved for earlier-stage NSCLC.

A total of 935 people with NSCLC enrolled in EA5142/ANVIL from May 2016 to September 2019. After receiving post-surgery chemotherapy and/or radiation therapy, participants were randomly assigned by a computer to one of two treatment groups:

1. Usual care: regular monitoring with blood tests and CT scans
2. Study treatment: nivolumab given every 4 weeks for up to 1 year

Patients receiving nivolumab could stop treatment if side effects became too severe or their cancer returned. After completing 1 year of monitoring or nivolumab treatment, all participants continued to be followed by their doctor for up to 10 years.

What are the results?

- Nivolumab did not meaningfully increase the amount of time participants lived without their cancer returning compared with observation alone. The median was approximately 71 months for participants who received the study drug and 69 months for those who received observation alone.
    - 25% of participants who received nivolumab experienced serious side effects. These included inflammation of the lungs (pneumonitis), diarrhea, rash, and trouble breathing.

What do the results mean for patients?

- The study found that adding nivolumab after surgery and standard treatment did not lessen the chance of the cancer coming back after surgery.
- Participants who received nivolumab were also more likely to experience serious side effects than those who received observation alone.
- Although nivolumab did not provide benefit, the results answered an important question and will help guide future research to improve therapies for people with early-stage NSCLC.

NCI National Clinical Trials Network
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For more information, go to:

- United States National Institutes of Health (NIH) Library of Medicine: https://clinicaltrials.gov/study/NCT02595944
- *The Journal of the American Medical Association (JAMA):* https://jamanetwork.com/journals/jama/fullarticle/2849808

About ECOG-ACRIN

This trial was led by the ECOG-ACRIN Cancer Research Group (ECOG-ACRIN). ECOG-ACRIN is a membership-based scientific organization that designs and conducts cancer research involving adults who have or are at risk of developing cancer. ECOG-ACRIN is a component of the National Cancer Institute's National Clinical Trials Network. Learn more at www.ecog-acrin.org.

To all the patients that participated in this trial, thank you. Your participation, and that of other patients like you, made this research possible.