Adjuvant Nivolumab in Resected Lung Cancers (ANVIL): A Randomized Phase III Study of Nivolumab After Surgical Resection and Adjuvant Chemotherapy in Non–Small Cell Lung Cancers

Why this study is being done

• The purpose is to find out whether adding a new drug, nivolumab (Opdivo®), after surgery and the usual postoperative treatment can stop lung cancer from coming back
  - Nivolumab may turn on the immune system to attack cancer cells left behind after surgery
  - This trial will help researchers determine whether treatment with nivolumab is better, the same, or worse than observation after the usual treatment
  - This trial will monitor the side effects of nivolumab after lung cancer surgery and the usual postoperative treatment
  - Nivolumab has been approved by the Food and Drug Administration (FDA) to be given to patients who already had chemotherapy for their non–small cell lung cancer (NSCLC); the FDA has given permission for its use in this study for early-stage NSCLC

Who can take part in the study—your eligibility*

Approximately 714 people in the United States will take part in this study. Some requirements for participating are as follows:

• Take part in the ALCHEMIST Screening Trial to determine mutational status
• No mutation in EGFR and ALK cancer markers
• Age at least 18 years and had surgery for your lung cancer
• Liver and blood test results at an acceptable level (2 weeks before study)
• No HIV or hepatitis
• No allergy to nivolumab
• Not pregnant or breastfeeding while taking nivolumab

*These are the main requirements only. Your doctor will perform a more detailed review of your eligibility if you are interested in participating.

What this study involves

Once enrolled in this study, you will be assigned to a treatment group by chance (randomized), as shown in the diagram. If assigned to nivolumab, you will receive treatment once every 4 weeks. Your treatment will continue for up to 1 year or until you have side effects, your cancer returns, or you decide to stop. Once treatment has finished, your doctor will continue to follow your condition for up to 10 years; follow-up will include CT scans of your chest.

For Further Study Information

• For more information about the EA5142 study, please visit the following:
  - Cancer.gov; search EA5142
  - Clinicaltrials.gov; search NCT02595944
• For more information about ECOG-ACRIN, visit ecog-acrin.org

EA5142 Patient Study Summary v.04/20/18