A Randomized Phase III Study of Maintenance Therapy With Bevacizumab, Pemetrexed, or a Combination of Bevacizumab and Pemetrexed Following Carboplatin, Paclitaxel, and Bevacizumab for Advanced Non-squamous Non–Small Cell Lung Cancer (NSCLC)

Why this study is being done

- This study is being done to find out if the addition of long-term therapy to standard chemotherapy increases the survival of patients with advanced nonsquamous NSCLC. Although the survival rate in patients with NSCLC is improved with standard combination chemotherapy, we want to see if adding another therapy will improve the length of life for patients with NSCLC.
- The study has several purposes:
  - To compare survival and response rates following maintenance therapy with bevacizumab, pemetrexed, or a combination of bevacizumab with pemetrexed.
  - To examine safety and tolerability with these maintenance therapies.
  - To examine possible biomarkers that may predict a patient’s response to a specific treatment.
- All drugs used in the study have been approved by the Food and Drug Administration (FDA).

What this study involves

Once enrolled in this study, all patients will receive initial combination chemotherapy (induction therapy). Responding patients following initial combination chemotherapy will be randomized to 1 of 3 maintenance study treatments (maintenance therapy), as shown in the diagram. The diagram reviews when exams need to be completed and when medication will be given.

Who will take part in the study—your eligibility*

There will be 1495 people who will participate in this study. There are some requirements to be able to enroll as a participant. This is a phase III trial which enrolls the largest group of patients. All of the therapies in this study have been tested in humans and safety standards have been established.

- 18 years old or older with confirmed advanced-stage nonsquamous NSCLC.
- Properly working organs.
- Controlled high blood pressure (no higher than 150/100).
- No pregnancy or breast-feeding.
- No prior treatment (eg, paclitaxel, pemetrexed, or bevacizumab) for NSCLC.
- No prior systemic chemotherapy for advanced-stage lung cancer.
- Prior adjuvant (additional) chemotherapy is allowed if at least 12 months have passed since prior chemotherapy administration and registration.
- No major coughing up blood within 4 weeks prior to study registration (defined as bright red blood of ½ teaspoon or more).
- No prior cancers within the past 3 years (except mild cases of some skin cancers).
- No actively progressive brain metastases, serious illnesses, active infection, symptomatic congestive heart failure, unstable chest pain, serious cardiac irregular heart rate, or mental illness.
- No major surgery or serious injuries within 6 weeks of deciding to participate in this study.

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