Comparing Treatments for High Risk, Early Stage Non-Small Cell Lung Cancer

What is the purpose of this clinical trial?

Surgery is the standard treatment for early stage non-small cell lung cancer. However, some people can’t get surgery to remove their lung cancer. Other people don’t want to have surgery. In these cases, the standard treatment is radiation, using a procedure called stereotactic body radiotherapy, or SBRT. This clinical trial is testing whether SBRT can be improved when used with a new cancer immunotherapy drug called a checkpoint inhibitor. Other clinical trials have found this immunotherapy can be effective in treating non-small cell lung cancer, and that it may work well if used with radiation. This study aims to find out whether SBRT plus a checkpoint inhibitor is a better treatment.

This trial is set up to find out:

- How long participants survive in each group at the end of the five-year study period
- How long people remain cancer free in the two treatment groups, and if participants have any side effects from taking the study medicine

Why is this trial important?

This trial is important because even after SBRT, non-small cell lung cancer may return. Doctors want to find a better way to treat people so that they live longer, healthier lives. Other trials have shown that this new type of immunotherapy, called a checkpoint inhibitor, can benefit people with non-small cell lung cancer. There is also some evidence that checkpoint inhibitors work well, and are safe, when given along with radiation treatments. This is one of the largest studies so far to test this idea in people with high risk, early stage non-small cell lung cancer.

Who can be in this trial?

This trial is for men and women over the age of 18, with stage 1 or 2 non-small cell lung cancer. The cancer cannot have spread to lymph nodes or any other part of the body.

This trial may be for people who:

- Have proven stage 1 or 2 non-small lung cancer
- Are at higher risk for their cancer growing and spreading based on the size of their tumor, or other tumor features
- Have no evidence of their cancer spreading to another part of their body
- Cannot or will not have lung cancer surgery

This trial is not for people who:

- Have a major infection, an autoimmune disease, or a current or past case of hepatitis B, hepatitis C, or HIV
- Are pregnant
- Have a history of certain types of serious lung disease
What treatments would I get?

Doctors divide participants into two groups. One receives the radiation therapy, and the other receives radiation therapy plus the immunotherapy study medicine. Your doctor will not have control over which group you’d be assigned to, which helps produce trial results that are fair and reliable.

What is the time commitment?

For participants taking the study drug, treatment will last up to 168 days, or nearly six months. For all participants, the trial will include follow-up tests and health checks for a total of five years. To be a good candidate for this trial, you must be able to commit to the full five years of the study.

Are there costs? Will I get paid?

Cost of the trial medicine will be paid for by Genentech, which makes the checkpoint inhibitor. Insurance companies usually pay for SBRT treatment, because it is standard. Please check with your healthcare provider and insurance provider to find out what costs will – and won’t – be covered. You will not be paid for joining the study.

Where can I find more information about this trial?

• For more information about this trial, speak with your health care provider or call the National Cancer Institute at 1-800-4-CANCER
• Go to www.ClinicalTrials.gov and search using 04214262

Key information

Protocol number: S1914
NCT number: 04214262
Full trial title: A Randomized Phase III Trial of Induction/Consolidation Atezolizumab (NSC #783608) + SBRT Versus SBRT Alone In High Risk, Early Stage Non-Small Cell Lung Cancer

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Thank you! When you participate in a clinical trial, you’re moving cancer medicine and patient care forward.