Lung cancer biomarker tried as screening tool, 10/15

Early results from a randomized trial for lung cancer using autoantibody biomarkers were announced at the International Association for the Study of Lung Cancer's 16th World Conference on Lung Cancer, held Sept. 6–9 in Denver. The initial results of the National Health Service Scotland-sponsored ECLS Study of 10,000 high-risk smokers were presented by Professor Frank Sullivan in meeting abstract No. 48, "Progress with a randomized controlled trial of the detection in blood of autoantibodies to tumor antigens as a case-finding method in lung cancer using the EarlyCDT-Lung test in Scotland."

The ECLS Study uses the Early CDT-Lung blood test developed by Oncimmune. The early results of the study demonstrate the cancer detection rate of 81 percent, which is considerably better than the test performance states at 41 percent. The positivity rate is as expected with a specificity of 91 percent. However, it should be noted that the control arm has not been formally assessed. The final data on the control arm will be collected at the end of the study.

First announced in March 2012, the study is designed to determine whether use of the EarlyCDT-Lung blood test leads to earlier detection of lung cancer and can help save lives in the long term. The rationale is that patients preidentified as being at high risk of lung cancer take the EarlyCDT-Lung blood test. Those who receive a positive result are effectively triaged into a much higher risk group and are referred for x-ray and low-dose CT scan. This high-risk selection protocol results in many fewer low-dose CT scans but with the same, already established National Lung Screening Trial mortality benefit of low-dose CT scans.

Further interim results will be announced over the next three years with final publication expected in 2018 or 2019. These study results will enable the NHS to make a decision about whether to offer the EarlyCDT-Lung blood test as a nationwide screening test in the future and may enable the adoption of EarlyCDT-Lung screening by other countries. Recruitment will continue until a total of 12,000 patients have been enrolled to ensure robust, statistically significant results are achieved in the shortest time possible.

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