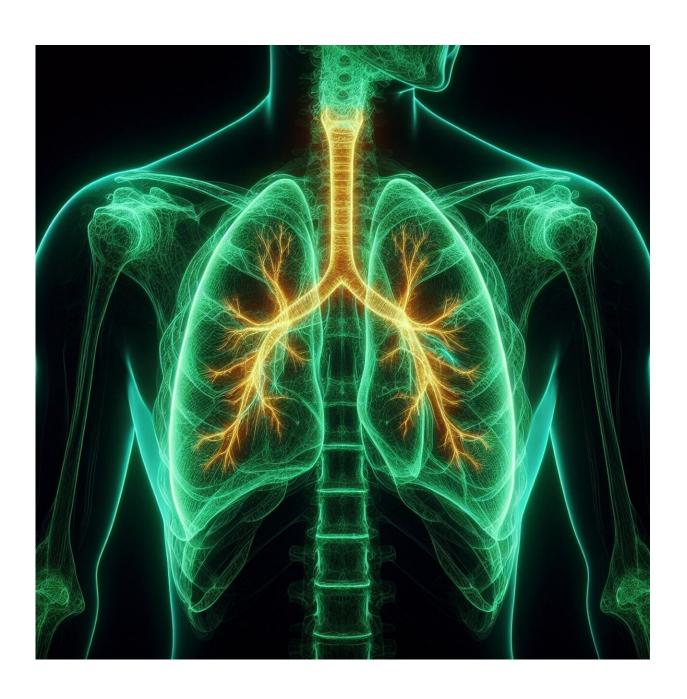


Pre- and post-surgical immunotherapy improves outcomes for patients with operable lung cancer, Phase III study finds

May 15 2024





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Compared with pre-surgical (neoadjuvant) chemotherapy alone, adding perioperative immunotherapy—given before and after surgery—significantly improved event-free survival (EFS) in patients with resectable early-stage non-small cell lung cancer(NSCLC), according to researchers from The University of Texas MD Anderson Cancer Center.

Results from the Phase III CheckMate 77T study were published today in the New England Journal of Medicine. At a median follow-up of 25.4 months, the median EFS with chemotherapy alone was 18.4 months, while the median had not yet been reached for patients receiving perioperative nivolumab, meaning EFS was prolonged significantly over the control group. These results correspond to a 42% reduction in risk of disease progression, recurrence, or death for those receiving the perioperative combination.

This data was first presented at the 2023 <u>European Society for Medical Oncology (ESMO) Congress</u>.

Patients who received the perioperative nivolumab-based regimen also saw significantly higher rates of pathological complete response (pCR), defined as no tumor remaining at surgery, compared with those who received chemotherapy alone (25.3% vs. 4.7%).

Rates of major pathological response (MPR), less than or equal to 10% of viable tumor cells remaining at time of surgery, were also higher in patients who received perioperative immunotherapy (35.4% vs. 12.1%).



"This study builds on the standard-of-care neoadjuvant chemoimmunotherapy treatment and supports perioperative nivolumab as an effective approach that reduces the risk of lung cancer relapse," said principal investigator Tina Cascone, M.D., Ph.D., associate professor of Thoracic/Head & Neck Medical Oncology.

"These findings add to evidence that the perioperative immunotherapy path gives patients with operable lung cancer an opportunity to live longer without their cancer returning."

Roughly 30% of patients diagnosed with NSCLC have operable disease, meaning their tumor can be removed by a surgical operation. While many of these patients can be potentially cured by surgery, more than half will experience cancer recurrence without additional therapy. Chemotherapy given either before or after surgery provides only a minimal survival benefit.

The randomized, double-blind <u>CheckMate 77T trial</u>, which began in 2019, included more than 450 NSCLC patients over the age of 18 from around the globe. Participants were randomized to treatment with either neoadjuvant nivolumab with chemotherapy followed by surgery and adjuvant nivolumab, or <u>neoadjuvant chemotherapy</u> and placebo followed by surgery and adjuvant placebo

The data showed no new safety signals with the perioperative nivolumab regimen and is consistent with the known safety profiles of individual agents. Grade 3-4 treatment-related side effects were observed in 32% and 25% of patients receiving the perioperative combination or control therapy, respectively. Surgery-related adverse events occurred in 12% of patients in both treatment arms.

These findings add to recent success seen with neoadjuvant nivolumab plus chemotherapy in NSCLC. In March 2022, the Phase III CheckMate



<u>816 study</u> led to FDA approval of <u>nivolumab</u> combined with <u>platinum-based chemotherapy</u>.

"I am enthusiastic about the initial findings of the study," Cascone said.
"Looking ahead, it will be critical to identify patient and disease characteristics that will tell us who can potentially be cured with neoadjuvant chemoimmunotherapy only and who will benefit from more intensified treatment strategies."

More information: *New England Journal of Medicine* (2024). www.nejm.org/media/doi/full/10.1056/NEJMoa2311926

Provided by University of Texas M. D. Anderson Cancer Center

Citation: Pre- and post-surgical immunotherapy improves outcomes for patients with operable lung cancer, Phase III study finds (2024, May 15) retrieved 23 June 2024 from https://medicalxpress.com/news/2024-05-pre-surgical-immunotherapy-outcomes-patients.html

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