

NADIM II trial provides support for neoadjuvant chemoimmunotherapy for patients with non-small cell lung cancer

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Dr. Mariano Provencio, Hospital Universitario Puerta de Hierro-Majadahonda, Spain. Credit: Dr. Mariano Provencio, Hospital Universitario Puerta de Hierro-Majadahonda, Spain

In the initial [NADIM](#) trial, neoadjuvant chemoimmunotherapy was shown to be highly effective in patients with resectable stage IIIA non-small cell lung cancer. Today, the researchers from the NADIM trial present new data that supports the conclusions of the initial NADIM trial.

To develop additional data to follow up on NADIM, Dr. Mariano Provencio, Hospital Universitario Puerta de Hierro-Majadahonda, Spain and colleagues at several Spanish medical sites, created NADIM II (NCT03838159), an open-label, randomized, two-arm, phase II, multi-center clinical trial sponsored by the Spanish Lung Cancer Group (GECp).

NADIM II enrolled patients with resectable clinical stage IIIA (per AJCC 7th edition) NSCLC, ECOG PS 0-1, and no known EGFR/ALK alterations were randomized to receive nivolumab 360mg + paclitaxel 200mg/m² + carboplatin for three cycles every 21 days (+/- 3 days) as neoadjuvant treatment followed by surgery, or paclitaxel 200mg/m² + carboplatin for three cycles every 21 days (+/- 3 days) followed by surgery.

Patients with R0 resection confirmed by pathological evaluation-initiated adjuvant administration of nivolumab (480 mg Q4W) within the third to eighth week (+ 7 days) from surgery and for six months. The primary endpoint was pathological complete response (pCR) and progression-free survival (PFS), overall survival (OS) and biomarker analysis are secondary endpoints of the trial.

Median follow-up time was 21.9 months (95%CI: 18.7-23.3). At the time of data cutoff (March 2021), [progression-free survival](#) at 24 months was 67.3% (95%CI: 55.5-81.6) for patients treated with nivolumab plus chemotherapy versus 52.6% (95%CI: 36.8- 75.2) for patients treated with chemotherapy (hazard ratio: 0.56; 95%CI: 0.28-1.15; P= 0.117).

Overall survival at 24 months was 85.3% (95%CI: 75.7-96.1) with nivolumab plus chemotherapy versus 64.8% (95%CI: 47.4-86.4) with chemotherapy (hazard ratio, 0.37; 95%CI, 0.14-0.93; P=0.003). In the experimental arm, PDL1 expression ($\geq 1\%$) significantly identified patients with improve PFS (HR: 0.26; 95%CI: 0.08-0.77; P = 0.015). Pathological complete response (pCR) rate was 36.2% in the experimental arm versus 6.8% in the control arm (P = 0.007). None of the patients showing a pCR has progressed or deceased (P LogRank

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