

Paclitaxel and gemcitabine versus carboplatin and gemcitabine in patients with advanced non-small-cell lung cancer. A phase III study of the Hellenic Cooperative Oncology Group.

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Source

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Abstract

BACKGROUND:

This phase III study was designed to compare the combination paclitaxel (Taxol)-gemcitabine (PG) versus carboplatin-gemcitabine (CG) in patients with advanced inoperable non-small-cell lung cancer.

METHODS:

Chemotherapy-naive patients with performance status of zero or one were randomized to gemcitabine 1 gm/m² on days 1 and 8 plus either paclitaxel 200 mg/m² on day 1 (arm A) or carboplatin at an area under the concentration-time curve of 6 mg on day 1 (arm B) every 3 weeks. Primary end point was overall survival (OS). Secondary end points included objective response (OR), time to progression and toxicity.

RESULTS:

A total of 512 patients were enrolled and 452 eligible (arm A, 225; arm B, 227) were analyzed. All characteristics were well balanced with the exception of vena cava obstruction symptoms and lymph node involvement. Median survival was 9.97 months [95% confidence interval (CI) 8.74-12.0] for group A and 10.49 (95% CI 9.04-11.94) for group B. There was no difference in the OS, 1-year survival, OR and TtP. However, statistically significant differences were seen in toxicity.

CONCLUSION:

The two regimens are equally active. Myelotoxicity is worse in the CG group whereas alopecia, myalgia and neurotoxicity worse in the PG group.