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Combination chemotherapy with paclitaxel plus carboplatin versus paclitaxel plus gemcitabine in inoperable non-small cell lung cancer: a phase III randomized study. Preliminary results. Hellenic Cooperative Oncology Group.

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Source

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Abstract

Gemcitabine plus paclitaxel and paclitaxel plus carboplatin are active and well tolerated in patients with advanced non-small cell lung cancer, showing similar rates of response and survival. The Hellenic Cooperative Oncology Group conducted a randomized phase III trial comparing gemcitabine plus paclitaxel with paclitaxel plus carboplatin. Patients were randomly assigned to two groups. Group A received paclitaxel 200 mg/m² plus carboplatin (area under the curve = 6) on day 1. Group B received paclitaxel in identical fashion to group A plus gemcitabine 1,000 mg/m² on days 1 and 8 every 3 weeks. A minimum of two cycles and a maximum of six cycles was allowed. To date, 127 eligible patients (63 in group A and 64 in group B) have been randomized; the median follow-up time is 4.6 months. Preliminary results suggest that both combinations can be given in full doses and are well tolerated. Grade 3/4 neutropenia was mild but more prominent in group A (10% v 3%, respectively) while thrombocytopenia was not significant for either group. Moreover, severe neurotoxicity, hepatotoxicity, or cardiac toxicity has not been observed in the vast majority of patients in either group. Although patients in group B experienced higher response rates (37.5%) than those in group A (21.8%), the difference between the groups was not statistically significant. Definite conclusions about this study cannot be made until more data are available.