

Weekly docetaxel with or without gemcitabine as second-line chemotherapy in paclitaxel-pretreated patients with metastatic breast cancer: a randomized phase II study conducted by the Hellenic Co-Operative Oncology Group.

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Source

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Abstract

OBJECTIVE:

A randomized phase II trial was conducted to test whether the addition of gemcitabine to weekly docetaxel could improve the objective response rate and survival outcomes as second-line chemotherapy in patients with metastatic breast cancer who have failed a paclitaxel-containing regimen.

METHODS:

Patients were randomized to receive either weekly docetaxel 40 mg/m² (group A, n = 34) or the combination of weekly docetaxel 35 mg/m² with gemcitabine 600 mg/m² (group B, n = 41). Three consecutive weekly infusions followed by a 1-week rest period represented 1 chemotherapy cycle.

RESULTS:

The objective response rate was 18% and 27.5% in group A and B, respectively (p = 0.413). No statistically significant differences were demonstrated in terms of median overall survival and time to disease progression. The rate and grade 3 and 4 neutropenia were higher in group B (23 vs. 3%).

CONCLUSIONS:

The weekly administration of docetaxel and gemcitabine did not result in superior clinical outcomes over weekly docetaxel.