

**Gemcitabine plus pegylated liposomal doxorubicin in patients with advanced epithelial ovarian cancer resistant/refractory to platinum and/or taxanes. A HeCOG phase II study.**

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**Source**

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**Abstract**

**BACKGROUND:**

A phase II study was conducted to evaluate the efficacy and toxicity of the combination of gemcitabine (GEM) and pegylated liposomal doxorubicin (PLD) in patients with platinum- and/or taxane-resistant/refractory advanced epithelial ovarian cancer (AEOC).

**PATIENTS AND METHODS:**

Patients (pts), who had been treated with platinum or paclitaxel and met the criteria of resistant/refractory AEOC, received GEM 650 mg/m<sup>2</sup> days 1 and 8 and PLD 25 mg/m<sup>2</sup> day 1 every 4 weeks up to a total of 6 cycles, unless disease progression or adverse effects prohibited further therapy.

**RESULTS:**

Thirty-seven patients entered the study. There was 1 complete (3%) and 7 partial responses (19%) for an overall response rate of 22%. Two patients had stable disease (5.5%). After a median follow-up of 16.2 months, the median survival was 8.4 months and time to treatment failure 2.7 months. The most frequent severe toxicity was myelosuppression recorded in 13 (35%) patients. Severe stomatitis was recorded in only 2 (5%) cases and severe palmar-plantar erythrodysesthesia in 1 patient. One severe allergic reaction (grade 4) to PLD was recorded following the third cycle of treatment.

**CONCLUSION:**

The combination of GEM and PLD in patients with AEOC, who are resistant/ refractory to platinum and/or Taxanes, did not show any superiority over monotherapy. However, in view of the acceptable toxicity profile, the above combination may deserve further investigation in a randomised setting.