

## **Pegylated Liposomal Doxorubicin versus Gemcitabine in Progressive or Recurrent Platinum-Resistant Ovarian Cancer (phase III study)**

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### **Abstract**

**Aim of the study:** to investigate the efficacy & tolerability, of pegylated liposomal doxorubicin (PLD) versus gemcitabine (Gem) in the salvage treatment of progressive or recurrent platinum-resistant ovarian cancer.

**Patients and Methods:** A randomized phase III study planned to compare PLD (40 mg/m<sup>2</sup> every 28 days) to Gem (1,250 mg/m<sup>2</sup> on days 1 & 8 every 21 days) in ovarian cancer patients who experienced failure after only one platinum/taxane protocol and who had recurrence or progression within 6 months after completion of primary treatment.

**Results:** Between Feb. 2008 and August, 2010, a total of 49 patients were enrolled, including 24 patients to the PLD arm (arm A) and 25 patients to the Gem arm (arm B). The study remained open to follow-up for survival and other information until July; 2011. Both arms were balanced for clinicopathologic characteristics. The median PFS in PLD arm was 4.5 months while that for Gem arm was 5 months ( $P=0.2$ ). Median OS for the PLD arm was 13 months while that for Gem arm was 12.5 months and the difference was not statistically significant ( $P=0.35$ ). There was no statistically significant difference between both treatment arms in the overall response rate (6 patients in each arm).both hematologic & non hematologic toxicities were comparable in the two treatment arms except for hand & foot syndrome which is significantly higher with PLD ( $P=0.02$ ).

**Conclusion:** PLD and Gem are effective agents in platinum-resistant epithelial ovarian cancer with no significant difference in the PFS, OS, and response rate. Also both agents have tolerable & similar toxicity profile with the exception of hand & foot syndrome which is significantly higher with PLD. Larger randomized studies are needed to confirm these results