

**EudraCT No. 2005-002801-22**  
**CCR2785 – CARBOX - Carboplatin Plus Xeloda Followed by Maintenance Xeloda**  
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**Professor Martin Gore**  
**Royal Marsden NHS Foundation Trust**

**Phase I feasibility study of Carboplatin + Capecitabine followed by maintenance  
Capecitabine in recurrent platinum-sensitive ovarian cancer**

Patients with platinum-sensitive relapsed ovarian cancer were treated with carboplatin (AUC5) and capecitabine 750mg per m<sup>2</sup> bd, days 1-21 q21. De-escalation doses were 625mg per m<sup>2</sup> (dose level -1) and 500mg per m<sup>2</sup> (dose level -2) according to toxicity.

21 patients were enrolled in the trial between March 2007 and February 2009 and 20 of these patients were evaluable for toxicity. The data demonstrated that 15 patients required dose de-escalation to levels -1 or -2. 50% of patients had a partial response with a further 30% of patients having stable disease. Median progression-free survival was 7 months.

The study conclusions were:

1. Major toxicities that resulted in dose de-escalation were grade 3 haematological toxicity (55%) and cardiac toxicity grade 3 (10%)
2. Maximum tolerated dose for this combination was carboplatin AUC5 and capecitabine 500mg per m<sup>2</sup> bd
3. This combination carboplatin plus capecitabine is active in patients with platinum-sensitive relapsed ovarian cancer

This trial was presented at the American Association of Clinical Oncology in 2009.

Reference

A. Montes, S. K. Sandhu, C. Rothermundt, I. Coombes, R. A'Hern, C. Keyzor, A. Thomas, S. Kaye, M. Gore

*Phase I feasibility study of carboplatin plus capecitabine followed by maintenance capecitabine in patients (pts) with recurrent platinum-sensitive epithelial ovarian cancer (EOC).*

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**Prof Martin Gore**  
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