OV21/PETROC: A Randomized Gynecologic Cancer Intergroup (GCIG) Phase II Study of Intraperitoneal (IP) vs. Intravenous (IV) Chemotherapy Following Neoadjuvant Chemotherapy and Optimal Debulking Surgery in Epithelial Ovarian Cancer

Co-Chairs Helen J MacKay and Diane Provencher
On behalf of the OV21/PETROC Investigators
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OV21/PETROC: Background and Rationale

- Epithelial ovarian cancer (EOC) is the 5th most common cancer in women

Do EOC patients who receive neoadjuvant chemotherapy followed by optimal cytoreductive surgery benefit from IP Chemotherapy?

- Increasing rates of neoadjuvant chemotherapy for EOC (approx. 40% in NCCN centres US)

OV21/PETROC: Schema

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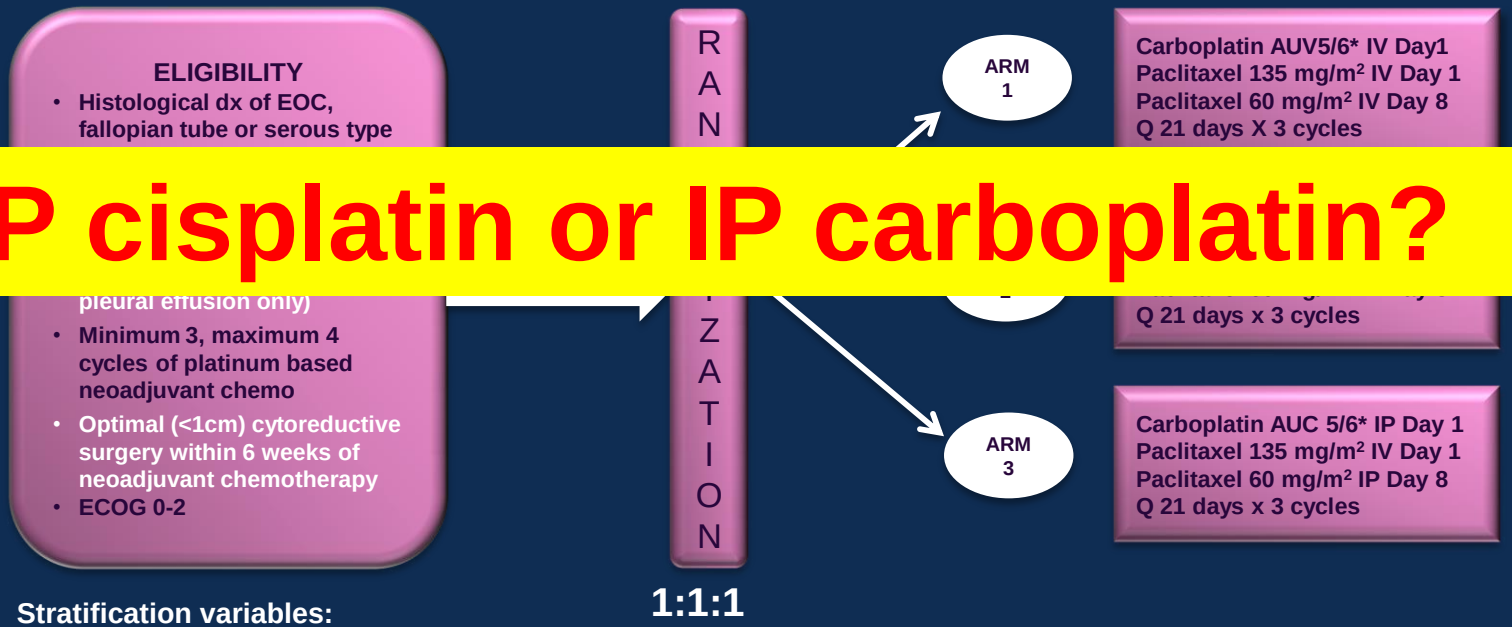

IP cisplatin or IP carboplatin?

Stratification variables:
- Cooperative group
- Residual disease: macroscopic vs. microscopic
- Reason for NACT: non-resectable disease vs. other
- Timing of IP catheter insertion: intra-operative vs. postoperative

* AUC 5 (measured GFR)/AUC 6 (calculated GFR)

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OV21/PETROC: Statistical Plan
First Stage: 3 Arm Phase II

"Pick the winner" design (N=50 each arm)

- 9-month progression rate post randomization. Futility/superiority rule

Assume that the 9-month PD rate in IV arm will be 40%. Stop trial if neither arm is at least 5% better. If only 1 arm is 5% better that is the one selected. If both IP arms meet the 5% better rule, select highest

- Completion rate of treatment
- Toxic effects
- Feasibility

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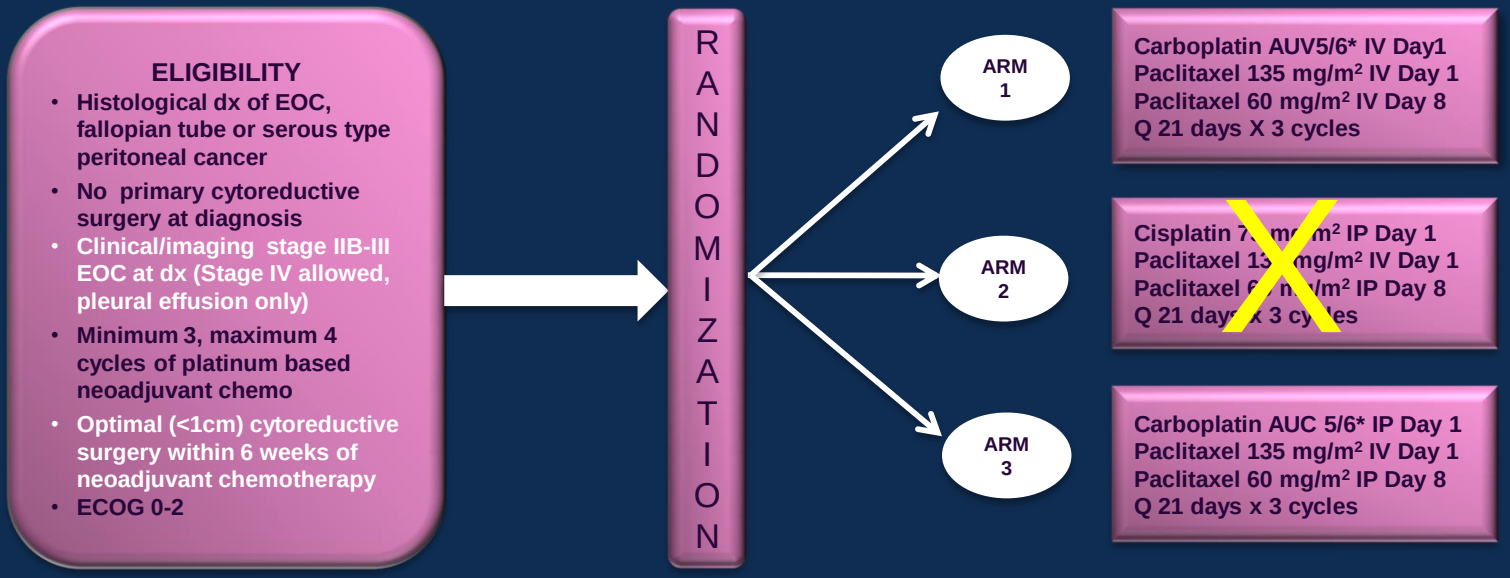

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OV21/PETROC: Statistical Plan Second Stage: Two Arm Expanded Randomized Phase II

- Originally planned as phase III study. Trial design modified to Phase II due to low accrual and funding issues
- **Primary endpoint** revised from PFS to **9 month PD rate post randomization** after consultation with DSMC

  Revised sample size 200 patients total (arms 1 and 3). 80% power to detect a 19% difference in progression rate at 9 months 2-sided, $\alpha=0.05$
- **Secondary endpoints:** Progression free survival (PFS), overall survival (OS), toxicity, quality of life, correlative laboratory studies, outcomes related to variation in nursing-related practices

OV21/PETROC: Study Conduct

- Activated September 2009
- Stage I accrual complete March 2013
- Analysis of stage I (n=150) January 2014
- Based on preplanned DSMC recommendation Stage 2 activated February 2014. Arm 2 (IP cisplatin) closed to accrual
- Key protocol amendment October 2014 to randomized phase II study, change in primary endpoint
- Closed to accrual May 2015
- Data cut off, February 28th 2016. Data analysis March 4th 2016

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OV21 ASCO 2016
Final Analysis

Oral Presentation

Sunday June 5th

Gynecologic Session

Oral Presentation

10:45 AM - 10:57 AM