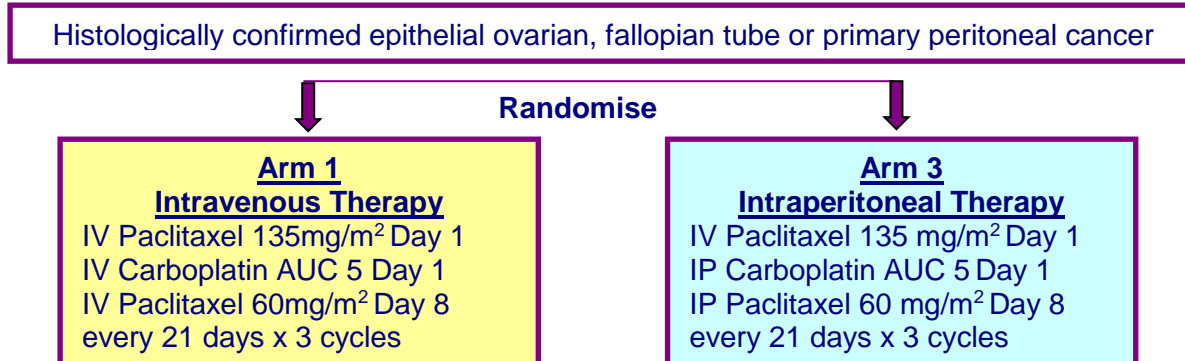


Aim: To determine if intraperitoneal (IP) platinum-based chemotherapy leads to improved 9 month progression rates post randomisation, progression free and overall survival as compared to intravenous (IV) chemotherapy in women who have had optimal debulking surgery following 3-4 courses of standard intravenous platinum based chemotherapy for newly diagnosed Stage IIB-III epithelial ovarian, peritoneal or fallopian tube cancer.

The phase initial II portion of the trial closed to recruitment on 03 February 2014 and we are now recruiting to the expanded phase II portion of the trial. Arm 2 was open at the initial phase II portion only.

Study Design – Expanded Phase II



Assessments: CT Scans carried out following last cycle of chemotherapy and 6 monthly for 2 years following treatment completion. Quality of Life assessments day 1 cycle 2, day 1 cycle 3, end of last cycle, 3, 6 and 12 months after end of protocol treatment.

The total expanded phase II sample size will be 200 patients, which will include 138 patients accrued to the initial phase II portion and an additional 62 patients accrued to the expanded phase II portion.

Primary Objective: 9 month Progression Rate Post Randomisation

Secondary Objectives: Progression free survival, Overall survival, Toxic effects, Quality of life, Correlative biological studies & Outcomes associated with variation in nursing-related practices

CONTACT DETAILS:

PETROC/OV21 Trial Co-ordinator ctc.PETROC@ucl.ac.uk Tel: 020 7679 9521; Fax: 020 7679 9871
Cancer Research UK & UCL Cancer Trials Centre, 90 Tottenham Court Road, London W1T 4TJ

Inclusion Criteria – Summary*

- Epithelial ovarian, fallopian tube or primary peritoneal cancer
- Completed 3-4 cycles of platinum-based neoadjuvant chemotherapy prior to surgery
- Debulking surgery must be after neoadjuvant chemotherapy, to include TAH, BSO, omentectomy and optimal de-bulking with residual disease 1cm or less
- Intraperitoneal catheter inserted at surgery or subsequent laparoscopy
- FIGO Stage IIB - III
- ECOG Performance Status 0-2
- Fit for treatment within 6 weeks of surgery
- Adequate haematological, renal and hepatic function
- Chest and abdominal/pelvic CT scan following debulking surgery and prior to start of protocol treatment
- Willingness to complete Q of L questionnaires

Exclusion Criteria – Summary*

- Previous course of treatment for epithelial ovarian, fallopian tube or primary peritoneal cancer
- Tumours of borderline or low malignant potential
- Patients with a mucinous tumour
- Previous malignancy, except adequately treated basal cell carcinoma of the skin or in situ cervix cancer with no evidence of disease for > 5 years
- Uncontrolled atrial or ventricular arrhythmias
- Myocardial infarction within the last 6 months
- Patients with a diagnosed bowel obstruction
- Concurrent treatment with other experimental drugs or anticancer therapy
- Serious condition/illness which would prevent patient being managed according to protocol

*Please consult protocol for full criteria list