

# A randomised trial of maintenance weekly paclitaxel versus observation following remission with first-line induction carboplatin and paclitaxel for patients with ovarian cancer

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|----------------------------------------|----------------------------------------|--------------------------------------------------------------------------------------------------------------|
| <b>Submission date</b><br>15/10/2002   | <b>Recruitment status</b><br>Stopped   | <input checked="" type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>15/10/2002 | <b>Overall study status</b><br>Stopped | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                       |
| <b>Last Edited</b><br>14/07/2014       | <b>Condition category</b><br>Cancer    | <input type="checkbox"/> Individual participant data<br><input type="checkbox"/> Record updated in last year |

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Protocol serial number**  
PACMAIN

## Study information

## **Scientific Title**

### **Study objectives**

It is intended that this study will run in the UK, mainland Europe and Australasia. If the study proves positive, it will require confirmation and will raise the question of whether weekly paclitaxel given for longer periods maybe even more effective.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

No ethics information required at time of registration.

### **Study design**

Randomised controlled trial

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Ovarian cancer

### **Interventions**

Maintenance chemotherapy: paclitaxel 70 mg/m<sup>2</sup> weekly, beginning three weeks after the last cycle of carboplatin/paclitaxel induction therapy and continuing for 15 weeks.

Updated 11/10/2012: please note that this trial never started due to a lack of funding.

### **Intervention Type**

Drug

### **Phase**

Not Applicable

### **Drug/device/biological/vaccine name(s)**

Carboplatin and paclitaxel

### **Primary outcome(s)**

Progression-free survival

### **Key secondary outcome(s))**

Not provided at time of registration

### **Completion date**

01/03/2005

**Reason abandoned (if study stopped)**

Lack of funding/sponsorship

## Eligibility

**Key inclusion criteria**

1. Histologically confirmed epithelial ovarian cancer, fallopian tube cancer and primary peritoneal cancer
2. Female, aged 18 years and over
3. International Federation of Gynecology and Obstetrics (FIGO) stage III to IV. Receive six cycles of carboplatin/paclitaxel, three-weekly at registration
4. Able to complete quality of life questionnaires
5. Can comply with follow-up requirements. Written informed consent
6. Response to induction treatment (as demonstrated by a Computed Tomography [CT] scan)

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

Female

**Key exclusion criteria**

1. Patients with peritoneal carcinomatosis of 'uncertain' origin which is mucin-secreting
2. Histological evidence of an origin in the gastrointestinal tract, biliary system or lung

**Date of first enrolment**

16/12/2002

**Date of final enrolment**

01/03/2005

## Locations

**Countries of recruitment**

United Kingdom

England

Australia

**Study participating centre**  
**Skin & Melanoma Unit**  
London  
United Kingdom  
SW3 6JJ

## **Sponsor information**

### **Organisation**

The Institute of Cancer Research (UK)

### **ROR**

<https://ror.org/043jzw605>

## **Funder(s)**

### **Funder type**

Research organisation

### **Funder Name**

The Institute of Cancer Research (UK)

## **Results and Publications**

### **Individual participant data (IPD) sharing plan**

### **IPD sharing plan summary**

Not provided at time of registration