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

Submission date 15/10/2002	**Recruitment status** Stopped	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 15/10/2002	**Overall study status** Stopped	
Last Edited 14/07/2014	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Ovarian cancer

Interventions
Maintenance chemotherapy: paclitaxel 70 mg/m^2 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 measure
Progression-free survival

Secondary outcome measures
Not provided at time of registration

Overall study start date
16/12/2002

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

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
1200

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, bilary system or lung

Date of first enrolment

16/12/2002

Date of final enrolment
01/03/2005

Locations

Countries of recruitment
Australia

England

United Kingdom

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

Sponsor information

Organisation
The Institute of Cancer Research (UK)

Sponsor details
123 Old Brompton Road
London
United Kingdom
SW7 3RP

Sponsor type
Government

Website
http://www.icr.ac.uk

ROR
https://ror.org/043jzw605

Funder(s)

Funder type

Research organisation

Funder Name
The Institute of Cancer Research (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration