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An international, five-arm randomised trial of carboplatin and paclitaxel versus triplet or sequential doublet combination in patients with epithelial ovarian cancer or primary peritoneal carcinoma

Submission date 18/05/2001	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 18/05/2001	**Overall study status** Completed	
Last Edited 22/10/2018	**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

ClinicalTrials.gov (NCT)
NCT00011986

Protocol serial number
E164/58

Study information

Scientific Title
An international, five-arm randomised trial of carboplatin and paclitaxel versus triplet or sequential doublet combination in patients with epithelial ovarian cancer or primary peritoneal carcinoma

Acronym
ICON5/GOG182

Study objectives
To evaluate a variety of chemotherapy regimes for patients with advanced stage (FIGO III-IV) epithelial ovarian or serious primary peritoneal carcinoma. Efficacy will be determined through analysis of overall survival and progression free survival.

The trial will also compare the toxicities and adverse effects of each treatment regimen, describe the dose density and collative dose delivery for each regime, compare response rates in patients with measurable disease. In the UK, evaluate the impact of regimes on quality of life, evaluate the impact of regimes on resource use and quality-adjusted life-years, collect and store genetic material for future studies of molecular genetics.

The trial includes two stages, at the end of the first stage only those treatment arms that appear promising on the basis of progression free survival will continue in to the second stage which aims to evaluate the impact of the regimes on overall survival.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Ovarian cancer and peritoneal carcinoma

Interventions
Arm I: Taxol 175 mg/m^2 day one, Carboplatin AUC6 or AUC(EDTA)5 iv day one, eight cycles
Arm II: Taxol 175 mg/m^2, day one, Gemzar 800 mg/m^2 days one and eight, Carboplatin AUC5 or AUC(EDTA)4, day one, eight cycles

Arm III: Taxol 175 mg/m^2 day one, Caelyx 30 mg/m^2 day one every other cycle, Carboplatin AUC5 or AUC(EDTA)4 day one, eight cycles
Arm IV: Hycamtin 1.25 mg/m^2 days one, two and three, Carboplatin AUC5 or AUC(EDTA)4 day three, four cycles, then four cycles of Arm I
Arm V: Gemzar 1000 mg/m^2, days one and eight, Carboplatin AUC6 or AUC(EDTA)5 day eight, four cycles then four cycles of Arm I

In every case cycles are 21 days long. Chemotherapy continues unless disease progression or unacceptable toxicity occurs. Dose reductions or delays for toxicity are defined in the full protocol.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Carboplatin and paclitaxel

Primary outcome(s)
Overall survival.

Key secondary outcome(s)
1. Progression free survival
2. Response rate (in patients with measurable disease)
3. Toxicity and symptoms
4. Dose and dose intensity
5. Patients assessment of quality of life and acceptability of treatment, health economics
6. Molecular genetics (future study)

Completion date
31/12/2007

Eligibility

Key inclusion criteria
1. Stage III or IV ovarian or serious primary peritoneal carcinoma, following appropriate surgery
2. Tumor tissue available for histological evaluation
3. Adequate bone marrow liver kidney and neurological function
4. World Health Organisation (WHO) performance status zero to two
5. Fit and able to take part in trial treatments and follow-up
6. Informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Concomitant or previous malignancies likely to interfere with protocol treatments
2. Patient has received radiotherapy or chemotherapy to any abdominal or pelvic tumour
3. Acute hepatitis, infection or Gastrointestinal bleeding
4. Women of childbearing age who will not use adequate contraception or are breastfeeding

Date of first enrolment
01/03/2002

Date of final enrolment
31/12/2007

Locations

Countries of recruitment
United Kingdom

England

United States of America

Study participating centre
Medical Oncology
London
United Kingdom
SE1 9RT

Sponsor information

Organisation
Medical Research Council (MRC) (UK)

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC) (UK)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results:	01/08/2003		Yes	No
Results article	results:	20/03/2009		Yes	No
Plain English results				No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes