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Phase I/II randomised study on pre-operative chemotherapy in advanced ovarian cancer

Submission date	Recruitment status	[ ] Prospectively registered
23/01/2004	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
23/01/2004	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
28/11/2019	Cancer	[ ] 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
845

Study information

Scientific Title
Phase I/II randomised study on pre-operative chemotherapy in advanced ovarian cancer

Study objectives

The proposed study will combine clinical and scientific approaches in trying to improve the treatment of patients with ovarian cancer. The purpose of this programme is to understand the factors promoting rapid tumour regrowth following surgical resection of ovarian cancer and to evaluate the usefulness of chemotherapy given during this period.
Aims: To identify the mitogenic agent(s) responsible for post-resection proliferation of tumour cells (the lead compounds are VEGF and LPA) and identify whether production is by tumour cells or during the wound healing response. In this way the researchers hope to identify antagonists for the mitogenic activity that could be developed as a treatment strategy.
To assess the safety of pre-operative carboplatin administration in patients with extra ovarian spread of the carcinoma at the time of surgery and the influence of this on survival of patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided 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
Following randomisation patients will receive intravenous carboplatin either: as per current practice or pre-operatively, at a dose calculated by Calvert's Formula. Patients will be reviewed in the clinic 2 weeks following surgery to discuss the pathological findings and to discuss the future management plan. Follow-up after completion of therapy will be 3 monthly for the first two years and 6 monthly until 5 years.

Intervention Type
Drug

Phase
Phase I/II

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

Primary outcome(s)
Not provided at time of registration

Key secondary outcome(s))
Not provided at time of registration

Completion date
01/10/1999

Eligibility

Key inclusion criteria
Recruitment target: 60 patients with extra-ovarian spread carcinoma randomised to pre-operative chemotherapy vs standard treatment

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Female

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/10/1997

Date of final enrolment
01/10/1999

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
City Hospital NHS Trust
Birmingham
United Kingdom
B18 7QH

Sponsor information

Organisation
NHS R&D Regional Programme Register - Department of Health (UK)

Funder(s)

Funder type
Government

Funder Name
NHS Executive West Midlands (UK)

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes