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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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/10/1997

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

Age group
Not Specified

Sex
Female

Target number of participants
60

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
England

United Kingdom

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)

Sponsor details
The Department of Health
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name

NHS Executive West Midlands (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