

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

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

Primary study design

Interventional

Study design

Randomised controlled trial

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