# 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	<ul><li>Record updated in last year</li></ul>

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

Mr Nigel Acheson

#### Contact details

City Hospital NHS Trust Dudley Road Birmingham United Kingdom B18 7QH

\_

abc@email.com

# 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 preoperative 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

# 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**

# **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