# A prospective, multicentre, randomised trial of carboplatin flat dosing vs. intrapatient dose escalation in first line chemotherapy of ovarian, fallopian tube and primary peritoneal cancers

Submission date 29/03/2004	<b>Recruitment status</b> No longer recruiting	<ul> <li>Prospectively registered</li> <li>Protocol</li> </ul>
<b>Registration date</b> 21/04/2004	<b>Overall study status</b> Completed	<ul> <li>[] Statistical analysis plan</li> <li>[X] Results</li> </ul>
Last Edited 19/10/2018	<b>Condition category</b> Cancer	Individual participant data

#### Plain English summary of protocol

http://cancerhelp.cancerresearchuk.org/trials/a-trial-comparing-the-same-dose-with-an-increasing-dose-of-carboplatin-for-ovarian-cancer

### **Contact information**

**Type(s)** Scientific

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## Additional identifiers

EudraCT/CTIS number

**IRAS number** 

ClinicalTrials.gov number NCT00098878

Secondary identifying numbers SCOTROC 4

## Study information

#### Scientific Title

A prospective, multicentre, randomised trial of carboplatin flat dosing vs. intrapatient dose escalation in first line chemotherapy of ovarian, fallopian tube and primary peritoneal cancers

#### Acronym

SCOTROC 4

#### **Study objectives**

Added 11/08/09:

The aim of this study is to determine whether intrapatient dose escalation of carboplatin gives superior progression-free survival to flat dosing of carboplatin in untreated ovarian cancer patients.

Please note that as of 11/08/09 this record has been extensively updated. All updates will appear in the relevant field with the above update date. Please also note that the sponsor information has been updated, initially the sponsor was listed as undefined.

Secondary sponsor: NHS Greater Glasgow and Clyde (NHSGGC) Board Dalian House PO Box 15329 350 St. Vincent Street Glasgow G3 8YZ

**Ethics approval required** Old ethics approval format

#### Ethics approval(s)

Added 11/08/09: Ethics approval from West Hertfordshire Research Ethics Committee on 06/10 /2003 (ref: MREC/3/3/40)

**Study design** Multicentre randomised active controlled parallel group 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

Advanced ovarian cancer

#### Interventions

Patients will be randomised to receive EITHER Carboplatin flat dose (no dose escalation) OR Carboplatin with an intra-patient dose escalation scheme based on nadir blood counts. The dose of Carboplatin in both arms for cycle 1 will be based on the glomerular filtration rate calculated by the Cockcroft-Gault formula, and dosed to an AUC of 6 by the Calvert formula.

#### Intervention Type

Other

**Phase** Not Specified

### Primary outcome measure

Added 11/08/09: Progression-free survival

#### Secondary outcome measures

Added 11/08/09: 1. Toxicity 2. Quality of life 3. Response rates (clinical and CA125) 4. Overall survival

Overall study start date 01/04/2000

Completion date 31/05/2005

# Eligibility

#### Key inclusion criteria

Current information as of 11/08/09:

1. Patients with histologically confirmed epithelial ovarian carcinoma, or primary fallopian tube carcinoma, considered unsuitable or unwilling for treatment with platinum-taxane combination therapy. Patients with peritoneal carcinomatosis (ovarian-type) are also eligible, without necessarily having histological proof of a primary source in the ovary, provided that the tumour is not mucin-secreting (see exclusion criteria).

2. Female, aged 18 or over.

3. FIGO stages Ic-IV with or without successful cytoreductive surgery at staging laparotomy. Stage Ic patients will be limited to those with malignant cells in ascitic fluid/peritoneal washings, tumour on the surface of the ovary, or pre-operative capsule rupture.

- 4. Written informed consent
- 5. Can comply with follow up requirements
- 6. Intention to treat patient within 8 weeks of initial surgery.

Initial information at time of registration:

Patients with histologically confirmed epithelial ovarian carcinoma (stage IC - IV), or primary fallopian tube carcinoma, considered unsuitable or unwilling for treatment with platinum-taxane combination therapy

#### Participant type(s)

Patient

#### Age group

Adult

### Lower age limit

18 Years

**Sex** Female

Target number of participants

1300 (Added 11/08/09)

#### Key exclusion criteria

Added 11/08/09:

1. ECOG performance > 3

2. Prior treatment with chemotherapy and radiotherapy

3. Inadequate bone marrow function defined as neutrophils < 1.5 or plateles < 100

4. Inadequate renal function as defined by calculated creatinine clearance (Cockcroft-Gault) of < 30ml/min. Obstructive hydronephrosis as a cause of "borderline" (eg 30-45 ml/min) renal function should be investigated and treated prior to study entry.

5. Inadequate liver function as defined by bilirubin > upper limit of normal or AST/ALT >2.5 x upper limit of normal or ALP > 5 x upper limit of normal.

6. Concurrent severe and/or uncontrolled co-morbid medical condition (i.e. uncontrolled infection, hypertension, ischaemic heart disease, myocardial infarction within previous 6 months, congestive heart failure)

7. Patient with mixed mesodermal tumours

- 8. Patients with boderline ovarian tumours or tumours termed "possibly malignant"
- 9. Adenocarcinoma of unknown origin, if histologically shown

#### Date of first enrolment

01/04/2000

#### Date of final enrolment

31/05/2005

### Locations

**Countries of recruitment** Scotland

United Kingdom

**Study participating centre Cancer Research UK Trials Unit** Glasgow United Kingdom G11 6NT

### Sponsor information

**Organisation** University of Glasgow (UK)

Sponsor details Cancer Research UK Clinical Trials Unit E Block Beatson Oncology Centre Western Infirmary Glasgow Scotland United Kingdom G11 6NT +44 (0)141 211 6287 j.paul@clinmed.gla.ac.uk

**Sponsor type** University/education

ROR https://ror.org/00vtgdb53

## Funder(s)

Funder type Charity

**Funder Name** 

Cancer Research UK (CRUK) (UK)

Alternative Name(s) CR\_UK, Cancer Research UK - London, CRUK

**Funding Body Type** Private sector organisation

**Funding Body Subtype** Other non-profit organizations

**Location** United Kingdom

**Funder Name** Scottish Gynaecological Cancer Trials Group (SGCTG) (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

#### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<u>Plain English results</u>				No	Yes
Results article	results	01/03/2013		Yes	No