ISRCTN47645935 https://doi.org/10.1186/ISRCTN47645935

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

Recruitment status
No longer recruiting

Registration date
21/04/2004

Overall study status
Completed

Last Edited
19/10/2018

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

Contact name
Dr Paul Vasey

Contact details
Cancer Research UK Trials Unit
E Block
Beatson Oncology Centre
Western Infirmary
Glasgow
United Kingdom
G11 6NT
+44 (0)141 211 2318/2009
p.vasey@beatson.gla.ac.uk

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?
Plain English results				No	Yes
Results article	results	01/03/2013		Yes	No