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Randomised study of two doses of cisplatin with cyclophosphamide in epithelial ovarian cancer

Submission date 01/07/2001	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 01/07/2001	**Overall study status** Completed	
Last Edited 02/02/2012	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr - -

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
G31

Study information

Scientific Title

Study objectives
Not provided at time of registration

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
1. Group A: Cisplatin 50 mg/m2 plus 750 mg/m2 cyclophosphamide repeated every 3 weeks for a maximum of six cycles
2. Group B: Cisplatin 100 mg/m2 plus 750 mg/m2 cyclophosphamide repeated every 3 weeks for a maximum of six cycles

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/1991

Completion date
01/03/1991

Eligibility

Key inclusion criteria
1. Confirmed diagnosis of invasive epithelial ovarian carcinoma including the following histological subtypes: Serous cystadenocarcinoma; Mucinous cystadenocarcinoma; Endometriod carcinoma; Clear cell (mesonephroid) carcinoma; Undifferentiated carcinoma
2. International Federation of Gynecology and Obstetrics (FIGO) stage Ic, II, III and IV
3. Age 18 -70 years
4. Eastern Cooperative Oncology Group (ECOG) performance status 0-2
5. Life expectancy of at least 3 months
6. Adequate bone marrow and renal function
7. No previous chemotherapy or radiotherapy
8. No history of previous malignancy, except adequately treated basal cell carcinoma of the skin or in situ carcinoma of the cervix
9. No serious intercurrent disease

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
Not provided at time of registration

Key exclusion criteria
Does not match inclusion criteria

Date of first enrolment
01/01/1991

Date of final enrolment
01/03/1991

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
UKCCCR Register Co-ordinator
London
United Kingdom
NW1 2DA

Sponsor information

Organisation
Cancer Research UK (CRUK) (UK)

Sponsor details
PO Box 123
Lincoln's Inn Fields
London
United Kingdom
WC2A 3PX
+44 (0)207 317 5186
kate.law@cancer.org.uk

Sponsor type
Charity

Website
http://www.cancer.org.uk

ROR
https://ror.org/054225q67

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

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?
Results article	results	08/08/1992		Yes	No