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

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr - -

Contact details

UKCCCR Register Co-ordinator MRC Clinical Trials Unit 222 Euston Road London United Kingdom NW1 2DA

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, Cancer Research UK (CRUK), 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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	08/08/1992		Yes	No