ISRCTN78953383 https://doi.org/10.1186/ISRCTN78953383

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

Submission date	Recruitment status	[_] Prospectively registered
01/07/2001	No longer recruiting	[_] 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

Protocol serial number
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

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

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(s)
Not provided at time of registration

Key secondary outcome(s)
Not provided at time of registration

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
Female

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
United Kingdom

England

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

Sponsor information

Organisation
Cancer Research UK (CRUK) (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

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