

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
Registration date 01/07/2001	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 02/02/2012	Condition category Cancer	☐ Individual participant data

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

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

Study design

Randomised controlled trial

Primary study design

Interventional

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; Endometrioid 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