

The role of radical surgery in advanced epithelial ovarian cancer

Submission date 01/07/2001	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 01/07/2001	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 30/10/2019	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

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
OV3006

Study information

Scientific Title

The role of radical surgery in advanced epithelial ovarian cancer

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

Patients are randomised to one of two treatment arms:

1. Arm A: High activity platinum based chemotherapy. The recommended chemotherapy regimen is cyclophosphamide and cisplatin given for a maximum of eight cycles.
2. Arm B: Radical debulking surgery followed by chemotherapy as described above.

Intervention Type

Mixed

Primary outcome measure

Not provided at time of registration

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/01/1990

Completion date

31/12/1995

Eligibility

Key inclusion criteria

1. Histologically confirmed epithelial ovarian cancer
2. Macroscopic residual disease unlikely in surgeon's opinion to be completely debulked without bowel resection or other procedures
3. No attempt to radically debulk
4. No prior chemotherapy or radiotherapy
5. No previous or concurrent malignancy other than non melanomatous skin cancer
6. No haematological or biochemical contra-indication to platinum chemotherapy
7. No contraindication to second laparotomy
8. Available to commence chemotherapy or undergo further surgery within 6 weeks of diagnostic laparotomy

Participant type(s)

Patient

Age group

Not Specified

Sex

Female

Target number of participants

Not provided at time of registration

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/01/1990

Date of final enrolment

31/12/1995

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

MRC Clinical Trials Unit
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

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