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Chemotherapy with or without surgery in treating patients with stage II or III ovarian cancer

Submission date 06/04/2000	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 06/04/2000	**Overall study status** Completed	
Last Edited 25/01/2019	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Ms Sarah Wheeler

Contact details
MRC Clinical Trials Unit
222 Euston Road
London
United Kingdom
NW1 2DA

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00003695

Secondary identifying numbers
OV06

Study information

Scientific Title
A randomised trial of interval debulking surgery in epithelial ovarian cancer suboptimally debulked at primary surgery

Study objectives
To determine the impact of interval debulking surgery in newly diagnosed ovarian cancer in patients with residual macroscopic disease after surgery.

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 to request a patient information sheet

Health condition(s) or problem(s) studied
Ovarian cancer

Interventions
One group interval debulking surgery/control

Intervention Type
Procedure/Surgery

Primary outcome measure
Survival, progression-free survival and quality of life

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/04/1998

Completion date
26/07/2001

Eligibility

Key inclusion criteria
1. Newly diagnosed, histologically confirmed epithelial ovarian cancer
2. International Federation of Gynecology and Obstetrics (FIGO) stage II, III or IV
3. Residual macroscopic disease more than 1 cm in diameter documented at primary surgery or post-operatively by imaging
4. Patient planned to receive platinum-based chemotherapy
5. Patient fit for interval debulking surgery
6. No concomitant or previous malignancy likely to interfere with protocol treatments or comparisons
7. Written informed consent

Participant type(s)
Patient

Age group
Not Specified

Sex
Female

Target number of participants
1000

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/04/1998

Date of final enrolment
26/07/2001

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

MRC Clinical Trials Unit
London
United Kingdom
NW1 2DA

Sponsor information

Organisation
Medical Research Council (MRC) (UK)

Sponsor details
20 Park Crescent
London
United Kingdom
W1B 1AL
+44 (0)20 7636 5422
clinical.trial@headoffice.mrc.ac.uk

Sponsor type
Research council

Website
http://www.mrc.ac.uk

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC) (UK)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

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