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North Thames CA125 study in advanced ovarian cancer

Submission date 01/07/2001	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 01/07/2001	**Overall study status** Completed	
Last Edited 27/09/2017	**Condition category** 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
NTOG4

Study information

Scientific Title
North Thames CA125 study in advanced ovarian cancer: a randomised controlled trial

Study objectives
Five versus eight courses of carboplatin or cisplatin in ovarian cancer.

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 schedules:
1. Schedule A: Carboplatin or cisplatin repeated every four weeks for a total of five courses. CA125 measurement to be carried out prior to each course.
2. Schedule B: Carboplatin or cisplatin repeated every four weeks for a total of eight courses. CA125 measurement to be carried out prior to each course.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Carboplatin, cisplatin

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
05/12/1989

Completion date
13/04/1994

Eligibility

Key inclusion criteria
1. Histologically confirmed diagnosis of invasive epithelial ovarian carcinoma
2. International Federation of Gynaecology and Obstetrics (FIGO) stage Ic, II, III or IV
3. Eastern Cooperative Oncology Group (ECOG) performance status 0 - 2
4. Aged 18 - 75 years
5. Adequate renal, hepatic and bone marrow function
6. Life expectancy of at least 3 months
7. No history of previous malignancy, except basal cell carcinoma of the skin or in situ carcinoma of the cervix
8. No medical contra-indications to protocol treatments

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
237

Key exclusion criteria
Does not comply with above inclusion criteria.

Date of first enrolment
05/12/1989

Date of final enrolment
13/04/1994

Locations

Countries of recruitment
England

United Kingdom

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

Sponsor information

Organisation
UK Co-ordinating Committee for Cancer Research (UKCCCR)

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

Sponsor type
Government

ROR
https://ror.org/054225q67

Funder(s)

Funder type
Not defined

Funder Name
Not provided at time of registration

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Follow-up results	01/04/1996		Yes	No