

North Thames CA125 study in advanced 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 checked="" type="checkbox"/> Results
Last Edited 27/09/2017	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Contact details
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Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Female

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**

United Kingdom

England

Study participating centre

UKCCCR Register Co-ordinator

London

United Kingdom

NW1 2DA

Sponsor information

Organisation

UK Co-ordinating Committee for Cancer Research (UKCCCR)

ROR

<https://ror.org/054225q67>

Funder(s)

Funder type

Not defined

Funder Name

Not provided at time of registration

Results and Publications

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