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Study of carboplatin based combination chemotherapy for good prognosis metastatic malignant teratoma

Submission date 28/02/2001	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 28/02/2001	**Overall study status** Completed	
Last Edited 11/09/2007	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
TE09

Study information

Scientific Title

Study objectives
To define equivalent activity and lower toxicity of combination chemotherapy containing carboplatin rather than cisplatin

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)
Not Specified

Health condition(s) or problem(s) studied
Cancer

Interventions
Arm 1 - 4 cycles BEP.
Arm 2 - 4 cycles CEB.

Intervention Type
Drug

Phase
Not Specified

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

Primary outcome(s)
Complete remission on chemotherapy or chemotherapy + surgery. Progression-free survival. Survival, toxicity.

Key secondary outcome(s))
Not provided at time of registration

Completion date
31/12/1993

Eligibility

Key inclusion criteria
Histologically confirmed non-seminomatous germ cell tumour of testis or combined seminoma /teratoma or seminoma with unequivocal raised serum alpha feto protein concentration

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

Key exclusion criteria
Previous chemotherapy.

Date of first enrolment
01/06/1989

Date of final enrolment
31/12/1993

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
MRC Clinical Trials Unit
London
United Kingdom
NW1 2DA

Sponsor information

Organisation
Medical Research Council (MRC) (UK)

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (UK)

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

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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	Results	01/05/1997		Yes	No