

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
Registration date 28/02/2001	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 11/09/2007	Condition category Cancer	☐ 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

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

Primary study design

Interventional

Study design

Randomised controlled trial

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