ISRCTN69711558 https://doi.org/10.1186/ISRCTN69711558

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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

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 measure

Complete remission on chemotherapy or chemotherapy + surgery. Progression-free survival. Survival, toxicity.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/06/1989

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

Age group
Not Specified

Sex
Not Specified

Target number of participants
450

Key exclusion criteria
Previous chemotherapy.

Date of first enrolment
01/06/1989

Date of final enrolment
31/12/1993

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
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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 (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	01/05/1997		Yes	No