ISRCTN14535482 https://doi.org/10.1186/ISRCTN14535482

Treatment of poor prognosis metastatic 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	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
29/10/2019	Cancer	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
TE13

Study information

Scientific Title
Treatment of poor prognosis metastatic teratoma

Study objectives
Determine whether treatment with the intensive regimen BOP/VIP-B is more effective than BEP /P.
To determine the effect of G-CSF on the proportion of patients receiving full dose intensity of combination chemotherapy with either regimen.

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
Metastatic teratoma

Interventions
Arm 1 - Without granulocyte colony stimulating factor (G-CSF), BEP/EP.
Arm 2 - Without G-CSF, BOP/VIP-B.
Arm 3 - With G-CSF, BEP/EP.
Arm 4 - With G-CSF, BOP/VIP-B.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)

Several

Primary outcome measure
Progression-free survival

Secondary outcome measures
Response rate, overall survival

Overall study start date
01/02/1991

Completion date
31/12/1994

Eligibility

Key inclusion criteria
Histologically proven non-seminomatous germ cell tumour

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
154

Key exclusion criteria
Previous radiotherapy or chemotherapy

Date of first enrolment
01/02/1991

Date of final enrolment
31/12/1994

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
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Sponsor type
Research council

Website
http://www.mrc.ac.uk

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC) (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