

Treatment of poor prognosis metastatic teratoma

Submission date 28/02/2001	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 28/02/2001	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 29/10/2019	Condition category Cancer	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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
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Sponsor information

Organisation

Medical Research Council (MRC) (UK)

Sponsor details

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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 (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