

# Treatment of poor prognosis metastatic teratoma

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