Treatment of high risk testicular tumour with high dose chemotherapy with peripheral blood stem cells

Submission date	Recruitment status	Prospectively registered
12/09/2003	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
12/09/2003	Completed	Results
Last Edited	Condition category	Individual participant data
20/04/2016	Cancer	[] Record updated in last year

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0063044257

Study information

Scientific Title

Treatment of high risk testicular tumour with high dose chemotherapy with peripheral blood stem cells

Study objectives

To assess the efficacy of high dose chemotherapy with peripheral blood stem cells to see if the response rate is improved compared to conventional therapy.

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

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Cancer: Testicular

Interventions

High dose chemotherapy with peripheral blood stem cells vs no high dose

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

- 1. Time to white cell and platelet recovery
- 2. Confirmation of response
- 3. Assessment of toxicity by standard World Health Organisation (WHO) grades

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/05/1994

Completion date

31/12/2008

Eligibility

Key inclusion criteria

- 1. Patients with histological proven non-seminomatous germ cell tumours
- 2. High risk factors as defined by MRC prognostic group

Participant type(s)

Patient

Age group

Not Specified

Sex

Male

Target number of participants

6

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/05/1994

Date of final enrolment

31/12/2008

Locations

Countries of recruitment

England

United Kingdom

Study participating centre Clinical Oncology Manchester

Manchester United Kingdom M20 4BX

Sponsor information

Organisation

Department of Health (UK)

Sponsor details

Richmond House 79 Whitehall London United Kingdom SW1A 2NL

Sponsor type

Government

Website

http://www.doh.gov.uk

Funder(s)

Funder type

Government

Funder Name

Christie Hospital NHS Trust (UK)

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 summaryNot provided at time of registration