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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
Dr PM Wilkinson

Contact details
Clinical Oncology
Christie Hospital NHS Trust
Wilmslow Road
Withington
Manchester
United Kingdom
M20 4BX
+44 0161 446 3261
Peter.Wilkinson@christie-tr.nwest.nhs.uk

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
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 summary

Not provided at time of registration