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Treatment of good prognosis germ cell cancer

Submission date 28/02/2001	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 28/02/2001	**Overall study status** Completed	
Last Edited 03/08/2009	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
TE20

Study information

Scientific Title

Study objectives
To compare 3 x BEP and 3 x BEP + 1 x EP and the five day schedule versus three days per cycle in good prognosis germ cell cancer

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

Study type(s)
Not Specified

Health condition(s) or problem(s) studied
Testicular cancer

Interventions
There are four groups:
1. The first receives three cycles of BEP chemotherapy over a five day schedule
2. The second group receives three cycles of BEP + 1 cycle of EP chemotherapy over a 5 day schedule
3. The third group receives three cycles of BEP over a 3 day schedule
4. The fourth group receives three cycles of BEP over a 3 day schedule plus one cycle of EP

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Several

Primary outcome(s)
1. Time to progression
2. Quality of life
3. Morbidity
4. Survival time

Key secondary outcome(s))
Not provided at time of registration

Completion date
01/05/1998

Eligibility

Key inclusion criteria

1. Seminoma or non-seminoma - testis or retroperitoneal primary, alpha-fetoprotein (AFP) ≤1000 iu/l human chorionic gonadotrophin (HCG) ≤5000 iu/l, lactic dehydrogenase (LDH) ≤1.5 x N
2. No liver, bone or brain mets seminoma - stage ≥2 C or relapse after radiotherapy and any primary site and LDH
3. No liver bone or brain mets

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Male

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/05/1995

Date of final enrolment
01/05/1998

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
MRC Clinical Trials Unit
London
United Kingdom
NW1 2DA

Sponsor information

Organisation
Medical Research Council (MRC) (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, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	15/03/2001		Yes	No
Results article	results	15/03/2003		Yes	No