ISRCTN35399995 https://doi.org/10.1186/ISRCTN35399995

# Treatment of good prognosis germ cell cancer

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

**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**
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

## 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
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 measure

1. Time to progression
2. Quality of life
3. Morbidity
4. Survival time

### Secondary outcome measures
Not provided at time of registration

### Overall study start date
01/05/1995

### 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

### Age group
Not Specified

### Sex
Male

### Target number of participants
800

### 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
England

United Kingdom

**Study participating centre**
**MRC Clinical Trials Unit**
London
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# Sponsor information

**Organisation**
Medical Research Council (MRC) (UK)

**Sponsor details**
20 Park Crescent
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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

### 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 |