

Treatment of good prognosis germ cell cancer

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Mrs Pat Cook

Contact details

MRC Clinical Trials Unit
222 Euston Road
London
United Kingdom
NW1 2DA
pat.cook@ctu.mrc.ac.uk

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

Primary study design

Interventional

Study design

Randomised controlled trial

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) $\leq 1.5 \times N$
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