ISRCTN37875250 https://doi.org/10.1186/ISRCTN37875250

One cycle of adjuvant bleomycin, etoposide, cisplatin (BEP) chemotherapy in high risk, stage one non-seminomatous germ cell tumours of the testis (NSGCTT)

Submission date
25/03/2009

Recruitment status
No longer recruiting

Registration date
14/05/2009

Overall study status
Completed

Last Edited
27/11/2025

Condition category
Cancer

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
http://www.cancerhelp.org.uk/trials/a-trial-single-cycle-chemotherapy-testicular-cancer-111-trial

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2008-006295-29

Integrated Research Application System (IRAS)
1866

ClinicalTrials.gov (NCT)

NCT01726374

Protocol serial number
ICR-CTSU/2008/10019

Study information

Scientific Title
A single group trial evaluating one cycle of adjuvant bleomycin, etoposide, cisplatin (BEP) chemotherapy in high risk, stage one non-seminomatous germ cell tumours of the testis (NSGCTT)

Acronym
111

Study objectives
111 is a single group trial of a single cycle of adjuvant bleomycin, etoposide, cisplatin (BEP500) chemotherapy in high risk stage one non-seminomatous germ cell tumours of the testis (NSGCTT). It aims to show a two year recurrence rate of less than 5%.

As of 22/02/2011 the anticipated end date for this trial has been updated from 01/06/2012 to 18 /03/2013.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South East REC, 20/08/2009, ref: 09/H1102/86

Study design
Non-randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Newly diagnosed non-seminomatous germ cell tumours of the testis (NSGCTT)/mixed germ cell tumours (MGCT) with vascular invasion and stage one disease

Interventions
Single cycle of adjuvant BEP chemotherapy comprising:
1. Cisplatin 50 mg/m^2 intravenous (IV) day 1 and day 2
2. Bleomycin 30,000 IU IV infusion day 1 or 2 and 30,000 IU IV/intramuscularly (IM) day 8 and day 15
3. Etoposide 165 mg/m^2 IV days 1, 2 and 3

Added 27/11/2025:
Additional Data Linkage Information:
Participants from this trial will also be included in the INTERACT project which will link to their data held by NHS England. For more information, please see the INTERACT website: https://www.icr.ac.uk/interact.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Bleomycin, etoposide, cisplatin (BEP) chemotherapy

Primary outcome(s)
Recurrence at 2 years (trial aims to show a 2 year recurrence rate of less that 5%).

Key secondary outcome(s))
1. Immediate and delayed toxicity (CTC) including long-term permanent infertility (greater than 2 years)
2. Contralateral second primary testicular germ cell malignancy
3. Relapse free survival
4. Overall survival

Measurement timings are between 4 - 5 years approximately with a yearly review of trial data by the Independent Data Monitoring Committee (IDMC).

Completion date
31/08/2019

Eligibility

Key inclusion criteria
1. Histologically proven non-seminomatous germ cell tumour (GCT) or mixed GCT (MGCT) of the testis
2. Histological proven vascular invasion of the primary tumour into the testicular veins or lymphatics
3. Clinical stage I patients (normal alpha-fetoprotein [AFP] and human chorionic gonadotropin [HCG], or optimum marker decline approaching normal levels after orchidectomy, no evidence of metastases on computed tomography [CT] of the chest, abdomen and pelvis)
4. Men aged greater than or equal to 16 years
5. Creatinine clearance greater than 50 ml/min
6. No previous chemotherapy
7. White blood cells (WBC) greater than 1.5 x 10^9/l and platelets greater than 100 x 10^9/l
8. Fit to receive chemotherapy
9. Able to start BEP chemotherapy as part of 111 study within 6 weeks* of orchidectomy
10. Written informed consent

*It is strongly recommended based on previous studies that adjuvant chemotherapy should start within 6 weeks of orchidectomy. However, if there are unavoidable delays this timescale can be extended to 8 weeks.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
16 years

Upper age limit
100 years

Sex
Male

Total final enrolment
246

Key exclusion criteria
1. All patients with seminoma
2. All patients with non-seminoma greater than clinical stage 1
3. All patients with no vascular invasion
4. Previous chemotherapy
5. Patients with second malignancy except contralateral testicular intraepithelial neoplasia (TIN) and contralateral germ cell tumour treated by orchidectomy and subsequent surveillance of more then 3 years
6. Co-morbidity precluding the safe administration of BEP chemotherapy
7. Patients with renal function impairment (creatinine clearance less than or equal to 50 ml/min)
8. Patients with liver function impairment (bilirubin greater than 1.25 x upper limit of normal [ULN] and/or aspartate aminotransferase [AST] greater than 2 x ULN)
9. Patients with pre-existing neuropathy
10. Patients with pulmonary fibrosis
11. Patients with serious illness or medical conditions incompatible with the protocol

Date of first enrolment
01/06/2009

Date of final enrolment
31/07/2014

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Department of Oncology
-
Birmingham
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Sponsor information

Organisation
Institute of Cancer Research (UK)

ROR
https://ror.org/043jzw605

Organisation
University Hospitals Birmingham NHS Foundation Trust

ROR
https://ror.org/014ja3n03

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK (CRUK) (UK)

Alternative Name(s)
CR_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2020	24/02/2020	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Plain English results				No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes