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	[X] Prospectively registered [_] Protocol
Registration date 14/05/2009	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 01/05/2020	**Condition category** Cancer	[_] Individual participant data

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

Study website
http://www.icr.ac.uk/research/research_sections/clinical_trials/clinical_trials_list/14702.shtml

Contact information

Type(s)
Scientific

Contact name
Prof Michael Cullen

Contact details
Department of Oncology
Queen Elizabeth Hospital
Edgbaston
Birmingham
United Kingdom
B15 2TH

Additional identifiers

EudraCT/CTIS number
2008-006295-29

IRAS number

1866

ClinicalTrials.gov number
NCT01726374

Secondary identifying numbers
ICR-CTSU/2008/10019, IRAS 1866

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-randomised controlled trial

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

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
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

Joint sponsor:
University Hospitals Birmingham NHS Trust (UK)
Research and Development
Queen Elizabeth Hospital
Queen Elizabeth Medical Centre
Birmingham, B15 2TH
United Kingdom

Intervention Type
Drug

Phase
Phase III

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

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

Secondary outcome measures
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).

Overall study start date
01/06/2009

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

Age group
Adult

Sex
Male

Target number of participants
236

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
England

United Kingdom

Study participating centre
Department of Oncology
Birmingham
United Kingdom
B15 2TH

Sponsor information

Organisation
Institute of Cancer Research (UK)

Sponsor details
123 Old Brompton Road
London
United Kingdom
SW7 3RP

Sponsor type
Research organisation

Website
http://www.icr.ac.uk/

ROR
https://ror.org/043jzw605

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK (CRUK) (UK)

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

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

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?
Plain English results				No	Yes
Results article	results	01/03/2020	24/02/2020	Yes	No
HRA research summary			28/06/2023	No	No