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Accelerated Bleomycin, Etoposide, Platinum (BEP) chemotherapy for intermediate and high risk metastatic germ cell tumour

Submission date 21/04/2008	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 16/05/2008	**Overall study status** Completed	
Last Edited 26/10/2018	**Condition category** Cancer	

Plain English summary of protocol
http://cancerhelp.cancerresearchuk.org/trials/a-trial-looking-at-two-weekly-bep-chemotherapy-for-germ-cell-tumours-in-men

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2004-000847-79

ClinicalTrials.gov (NCT)
NCT00453232

Protocol serial number
A090011

Study information

Scientific Title
A non-randomised phase II pilot study of Accelerated Bleomycin, Etoposide, Platinum (BEP) chemotherapy for intermediate and high risk metastatic germ cell tumours

Acronym
Accelerated BEP

Study objectives
To assess the tolerability and toxicity of an accelerated regimen of chemotherapy in patients with germ cell tumours.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Eastern Multicentre Research Ethics Committee, 07/04/2004, ref: 04/5/024

Study design
Multicentre non-randomised single-arm registration/interventional trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Metastatic germ cell tumour

Interventions
Day 1: etoposide (165 mg/m^2)/cisplatin (50 mg/m^2) (intravenous [IV] infusions)
Day 2: etoposide (165 mg/m^2)/cisplatin (50 mg/m^2)/bleomycin (30,000 units) (IV infusions)
Day 3: etoposide (165 mg/m^2)
Day 4: granulocyte colony-stimulating factor (G-CSF) injection (6 mg)
Day 6, 7 or 8: bleomycin (30,000 units) (IV infusion)
Day 10, 11 or 12: bleomycin (30,000 units) (IV infusion)

This is a single armed trial. Patients are followed-up according to institutional practice, however, the study requires computed tomography (CT), audiometry and lung function tests to be performed at one and two years post-chemotherapy.

Intervention Type
Drug

Phase
Phase II

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

Primary outcome(s)
The primary endpoint of feasibility will be judged by the results of all of the data via a risk-benefit analysis.

Toxicity will be assessed using the National Cancer Institute Common Terminology Criteria for Adverse Events (NCI-CTCAE) version 3.0 criteria during treatment, and then via CR51-EDTA for renal function (pre-treatment versus post-treatment). Audiometry and lung function tests (pulmonary vital capacity and diffusing capacity of the lung for carbon monoxide [DLCO]) are standard assessments performed. There is also a clinical assessment of neurotoxicity (including two-point discrimination, Romberg test, tendon reflexes and vibration test, along with NCI CTC neuropathy-motor toxicity and neuro-sensory toxicity assessments).

The patients are also given a simple questionnaire regarding tingling, burning and weakness they have experienced; its location, frequency and impact.

Key secondary outcome(s))
1. To establish the response rate to this treatment
2. To establish progression free survival

Completion date
01/08/2009

Eligibility

Key inclusion criteria
Patients must fulfill all of the following criteria in a particular category:

1. Non-seminoma germ cell tumour (intermediate risk):
1.1. Testis or retroperitoneal primary
1.2. Abnormal markers as below:
1.2.1. Alpha-fetoprotein (AFP) greater than 1,000 and less than 10,000 ng/ml
1.2.2. Human chorionic gonadotropin (HCG) greater than 5,000 and less than 50,000 iu/l
1.2.3. Lactate dehydrogenase (LDH) greater than 1.5 x to less than 10 x the upper limit of normal
1.3. No liver, bone, brain or other non-pulmonary visceral metastasis
1.4. Histological confirmation of non-seminomatous germ cell tumours (NSGCT) is not required if AFP or HCG are grossly elevated

2. Non-seminoma germ cell tumour (poor prognosis):
2.1. Mediastinal primary, or
2.2. Non-pulmonary visceral metastases, or
2.3. Poor markers - any of AFP greater than 10,000 ng/ml, HCG greater than 50,000 iu/l, LDH greater than 10 x upper limit of normal
2.4. Histological confirmation of NSGCT is not required if AFP or HCG are grossly elevated

3. Seminoma (intermediate prognosis):
3.1. Histological confirmation of seminoma is required
3.2. Any primary site
3.3. Non-pulmonary visceral metastases must be present

3.4. Normal AFP
3.5. Any HCG
3.6. Any LDH

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Male

Key exclusion criteria
1. Aged less than 18 years or over 40 years
2. Female patients
3. Previous malignancy except basal cell carcinoma of the skin
4. Previous chemotherapy or radiotherapy
5. Inadequate renal function - patients with creatinine clearance below 60 ml/min are excluded unless this is due to obstructive uropathy which can be relieved by nephrostomy
6. Neutrophils less than 1.0 x 10^9/L, platelets less than 100,000 prior to commencing treatment
7. Patient unable to understand and consent in English unless a full interpreter service is provided including translation of all documents or the provision of a tape recording of the consultation

Date of first enrolment
01/08/2004

Date of final enrolment
01/08/2009

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Addenbrooke's Hospital
Cambridge
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Sponsor information

Organisation
Cambridge University NHS Foundation Trust (UK)

ROR
https://ror.org/04v54gj93

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded (UK)

Funder Name
Amgen (UK) - providing discounted Neulasta® (pegfilgrastim) 6 mg/0.6 ml syringes

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	06/09/2011		Yes	No
Plain English results				No	Yes