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A randomised phase III toxicity study of day 2, 8, 15 short (30 minute) versus day 1, 2, 3 long (72 hours) infusion bleomycin for patients with International Germ Cell Cancer Collaborative Group (IGCCCG) good prognosis germ cell tumours, TE3

Submission date 20/09/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 01/12/2005	**Overall study status** Completed	
Last Edited 07/03/2019	**Condition category** Cancer	

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-chemotherapy-for-testicular-cancer

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)

NCT00324298

Protocol serial number
Version 4.1

Study information

Scientific Title
A randomised phase III toxicity study of day 2, 8, 15 short (30 minute) versus day 1, 2, 3 long (72 hours) infusion bleomycin for patients with International Germ Cell Cancer Collaborative Group (IGCCCG) good prognosis germ cell tumours, TE3

Acronym
TE3

Study objectives
This study aims to ascertain whether administering the same total dose of bleomycin by a continuous 72-hour infusion over the first three days of chemotherapy results in lower lung toxicity than if administered conventionally as weekly bolus injections.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Northern and Yorkshire Multi-Centre REC, 10/07/2003

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
IGCCCG Good Prognosis Germ Cell Tumours

Interventions
Day 2, 8, 15 short (30 minute) versus day 1, 2, 3 long (72 hours) infusion bleomycin.
In addition to standard care for patients on chemotherapy, which includes biochemical and radiological evaluation of disease, patients will also undergo lung function testing and computed tomography (CT) to assess pulmonary toxicity.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Bleomycin

Primary outcome(s)
Pulmonary toxicity, as confirmed by central radiological review of CT scans at 12 weeks after starting treatment

Key secondary outcome(s)
1. CT scan changes at 6 weeks
2. Quality of life
3. Changes in respiratory function tests
4. Treatment response
5. Progression-free and overall survival

Completion date
30/03/2011

Eligibility

Key inclusion criteria
1. Patients aged 16 - 50 inclusive
2. Patients with proven good risk metastatic germ cell cancer of the testis
3. Patients eligible for treatment with bleomycin, etoposide and cisplatin
4. Patients who are able to understand their participation in the study and give written consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Male

Key exclusion criteria
1. Patients who have had previous radiotherapy and/or chemotherapy
2. Patients with creatinine clearance less than 60 ml/min
3. Patients with a previous or concurrent second malignancy, except for basal cell skin cancer
4. Patients with any other major systemic illness
5. Impaired respiratory function i.e. shortness of breath on minimal exertion or hypoxia at rest, transfer coefficient for carbon monoxide (KCO), total lung capacity (TLC), forced expiratory volume in one second (FEV1) less than or equal to 60% predicted

Date of first enrolment
08/07/2003

Date of final enrolment

30/03/2011

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
St Bartholomew's Hospital
London
United Kingdom
EC1A 7BE

Sponsor information

Organisation
Barts and The London NHS Trust (UK)

ROR
https://ror.org/00b31g692

Funder(s)

Funder type
Charity

Funder Name
Orchid Cancer Appeal (UK)

Funder Name
Cancer Research UK (CRUK) (UK) - Clinical Trials Advisory and Awards Committee (CTAAC) grant

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	01/06/2017	07/03/2019	Yes	No
Plain English results				No	Yes