ISRCTN08648791 https://doi.org/10.1186/ISRCTN08648791

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

Contact name
Dr Jonathan Shamash

Contact details
Department of Medical Oncology
7th Floor
Gloucester House
St Bartholomew's Hospital
London
United Kingdom
EC1A 7BE

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number
NCT00324298

Secondary identifying numbers
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

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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 measure
Pulmonary toxicity, as confirmed by central radiological review of CT scans at 12 weeks after starting treatment

Secondary outcome measures
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

Overall study start date
08/07/2003

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

Age group
Adult

Sex

Male

Target number of participants
212

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
England

United Kingdom

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

Sponsor information

Organisation
Barts and The London NHS Trust (UK)

Sponsor details
Joint R&D Department
Barts & The London NHS Trust
Rutland House
New Road
London
England

United Kingdom
E1 2AX
+44 207 882 7260
gerry.leonard@bartsandthelondon.nhs.uk

Sponsor type
Hospital/treatment centre

Website
http://www.bartsandthelondon.nhs.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

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	01/06/2017	07/03/2019	Yes	No