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

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Contact details

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Additional identifiers

Clinical Trials Information System (CTIS)

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

Study design

Randomised controlled trial

Primary study design

Interventional

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Plain English results				No	Yes