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

EudraCT/CTIS number

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

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