ISRCTN53643604 https://doi.org/10.1186/ISRCTN53643604

Randomised phase II trial comparing intensive induction chemotherapy (CBOP BEP) with standard BEP chemotherapy in poor prognosis male germ cell tumours

Submission date
11/08/2004

Recruitment status
No longer recruiting

Registration date
22/10/2004

Overall study status
Completed

Last Edited
25/10/2022

Condition category
Cancer

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00301782

Clinical Trials Information System (CTIS)
2004-000405-22

Protocol serial number

Study information

Scientific Title
-

Acronym
TE23

Study objectives
Not provided at time of registration

More details can be found at: http://www.ctu.mrc.ac.uk/research_areas/study_details.aspx?s=38

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Male non-seminoma germ cell tumours (NSGCT)

Interventions
Patients will be randomly allocated either the 'gold standard' BEP (bleomycin, etoposide and cisplatin) chemotherapy or the intensive induction regimen CBOP/BEP (carboplatin, bleomycin, vincristine, cisplatin, etoposide).

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Bleomycin, carboplatin, cisplatin, etoposide phosphate, vincristine

Primary outcome(s)
Not provided at time of registration

Key secondary outcome(s)
Not provided at time of registration

Completion date
01/06/2010

Eligibility

Key inclusion criteria
1. Non-seminomatous germ cell tumour of any extracranial primary site
2. Poor prognosis features, as defined by the International Germ Cell Cancer Collaborative Group (IGCCCG) criteria
3. Performance status 0 - 3
4. Globular filtration rate greater than 50 ml/min
5. No comorbid condition

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Male

Total final enrolment
89

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/06/2005

Date of final enrolment
01/06/2010

Locations

Countries of recruitment
United Kingdom

England

Study participating centre

Institute of Cancer Research and Royal Marsden Hospital
Sutton
United Kingdom
SM2 5PT

Sponsor information

Organisation
Medical Research Council (MRC) (UK)

ROR
https://ror.org/03x94j517

Funder(s)

Funder type
Charity

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

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration

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	01/03/2015		Yes	No
Results article	results	01/03/2020	03/02/2020	Yes	No
Plain English results			25/10/2022	No	Yes