

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	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 22/10/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 25/10/2022	Condition category Cancer	<input type="checkbox"/> 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

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

2004-000405-22

IRAS number

ClinicalTrials.gov number

NCT00301782

Secondary identifying numbers

MRC TE23 Study, Version 1.0

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

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

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 measure

Not provided at time of registration

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/06/2005

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

Age group

Not Specified

Sex

Male

Target number of participants

88

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

England

United Kingdom

Study participating centre

Institute of Cancer Research and Royal Marsden Hospital

Sutton

United Kingdom

SM2 5PT

Sponsor information

Organisation

Medical Research Council (MRC) (UK)

Sponsor details

c/o Dr Ian Viney

MRC Centre London

Stephenson House

158-160 North Gower Street

London

United Kingdom

NW1 2ND

Sponsor type

Government

Website

<http://www.centre-london.mrc.ac.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

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**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