

Study of chemotherapy for patients with good prognosis metastatic non-seminomatous testicular cancer

Submission date 28/02/2001	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 28/02/2001	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 11/01/2019	Condition category Cancer	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

TE03

Study information

Scientific Title

Study of chemotherapy for patients with good prognosis metastatic non-seminomatous testicular cancer

Study objectives

Investigate whether the toxicity of chemotherapy in patients with small volume metastasis and low blood marker concentrations can be decreased by the reduction of the dose of Bleomycin given in the BEP regimen without loss of therapeutic activity.

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)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Cancer

Interventions

Arm 1: Bleomycin 30 mg x 3 per course, BEP x 4

Arm 2: Bleomycin 30 mg per course, BEP x 4

Intervention Type

Drug

Phase

Phase II

Drug/device/biological/vaccine name(s)

Bleomycin, etoposide, cisplatin (platinum)

Primary outcome measure

Toxicity/response

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/01/1986

Completion date

31/12/1986

Eligibility

Key inclusion criteria

Histologically proven non-seminomatous testicular cancer

Participant type(s)

Patient

Age group

Adult

Sex

Male

Target number of participants

44

Key exclusion criteria

Previous radiotherapy or chemotherapy

Date of first enrolment

01/01/1986

Date of final enrolment

31/12/1986

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

MRC Clinical Trials Unit

London

United Kingdom
NW1 2DA

Sponsor information

Organisation

Medical Research Council (MRC) (UK)

Sponsor details

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Sponsor type

Research council

Website

<http://www.mrc.ac.uk>

Funder(s)

Funder type

Research council

Funder Name

Medical Research Council (MRC) (UK)

Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

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