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

Submission date 28/02/2001	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 28/02/2001	**Overall study status** Completed	
Last Edited 11/01/2019	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Pat Cook

Contact details
MRC Clinical Trials Unit
222 Euston Road
London
United Kingdom
NW1 2DA
+44 20 7670 4600
pat.cook@ctu.mrc.ac.uk

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
20 Park Crescent
London
United Kingdom
W1B 1AL
+44 (0)20 7636 5422
clinical.trial@headoffice.mrc.ac.uk

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