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A study of computed tomography (CT) scan frequency in patients with stage I testicular teratoma

Submission date 06/04/2000	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 06/04/2000	**Overall study status** Completed	
Last Edited 28/10/2021	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.ctu.mrc.ac.uk/studies/TE08.asp

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT00003420

Secondary identifying numbers
TE08

Study information

Scientific Title
A study of computed tomography (CT) scan frequency in patients with stage I testicular teratoma

Study objectives
To assess the value of frequent abdominal and chest CT scans in the follow-up of patients with stage I non-seminomatous germ cell tumours (NSGCT) who are on a surveillance programme. After baseline scans confirming stage I disease, patients will be randomised between two and five further CT scans during their follow up, with the nature and frequency of all other investigations remaining constant.

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)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Cancer

Interventions
1. One group receives two CT scans
2. The other group receives five CT scans

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Stage of the disease at relapse (IGCC Classification), time from entry to detection of relapse.

Secondary outcome measures
Overall survival, identification of the first investigation or sign prompting diagnosis of relapse, incidence of second malignancies and balance of costs of treatment determined through health economics study

Overall study start date
01/12/1997

Completion date
30/04/2003

Eligibility

Key inclusion criteria
1. Histologically confirmed stage I non-seminomatous germ cell tumour of the testis
2. Patients must be able to attend for regular surveillance
3. The interval between orchidectomy and randomisation should not exceed 8 weeks
4. No co-existent or previously treated malignant disease, except successfully treated non-melanotic skin cancer

Participant type(s)
Patient

Age group
Not Specified

Sex
Male

Target number of participants
900

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/12/1997

Date of final enrolment
30/04/2003

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
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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 (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
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	10/04/2007		Yes	No
Plain English results			28/10/2021	No	Yes