ISRCTN56475197 https://doi.org/10.1186/ISRCTN56475197

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

Contact information

Type(s)
Scientific

Contact name
Miss Sharon Naylor

Contact details
MRC Clinical Trials Unit
222 Euston Road
London
United Kingdom
NW1 2DA
-
not@provided.com

Additional identifiers

ClinicalTrials.gov (NCT)
NCT00003420

Protocol serial number
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

Study type(s)
Not Specified

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

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Male

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
United Kingdom

England

Study participating centre
MRC Clinical Trials Unit
London
United Kingdom
NW1 2DA

Sponsor information

Organisation

Medical Research Council (MRC) (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, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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	10/04/2007		Yes	No
Plain English results			28/10/2021	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes