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

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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

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

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