

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

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|--|---|---|
| Submission date 06/04/2000 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 06/04/2000 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 28/10/2021 | Condition category Cancer | <input type="checkbox"/> Individual participant data |

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

Contact name

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Contact details

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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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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 (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 |