

A prospective comparison of two schedules of radiotherapy for stage I seminoma of the testis following orchidectomy

Submission date 28/02/2001	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 28/02/2001	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 20/12/2007	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

TE18

Study information

Scientific Title

Acronym

TE18

Study objectives

This trial was designed to compare the efficacy and the acute and long-term morbidity of standard radiotherapy with 30 Gy in 15 fractions versus 20 Gy in 10 fractions in patients with stage I seminoma testis.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Local ethical committee approval was obtained from each participating centre.

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

Stage I seminoma testis

Interventions

1. One group receives 30 Gy, given in 15 daily (Monday through Friday) fractions of 2 Gy
2. The other group receives 20 Gy in 10 daily fractions of 2 Gy

Follow-up assessments will take place every three months in year one, every four months in year two, every six months in year three, and annually until year ten. Clinical examination and serum tumors markers will be required at each visit; chest x-rays are required at the six, 12-, 20-, 30-, and 36-month visits; and Computed Tomography (CT) scans of chest, abdomen, and pelvis are required at the 12-, 24-, and 36-month visits.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Relapse-free rate, with relapse defined as the development of new masses (detected clinically or radiologically), or increasing tumor-specific markers (AFP, HCG).

Secondary outcome measures

Impact of dose on acute morbidity and quality of life.

Overall study start date

03/01/1995

Completion date

03/01/1998

Eligibility

Key inclusion criteria

1. Histologically confirmed seminomatous germ cell tumour of the testis that is categorised as either 'Classical' or 'Anaplastic'
2. Stage I disease, based on clinical and radiologic examination, and normal postorchidectomy Alpha-FetoProtein (AFP) and Human Chorionic Gonadotropin (HCG)
3. All 'T' categories of primary tumour are eligible except those with involvement of the cut end of the spermatic cord
4. Patients with previous inguino-pelvic or scrotal surgery, have to be treated with 'dog-leg' fields
5. The interval between orchidectomy and randomisation should not exceed eight weeks. Treatment should start within two weeks thereafter
6. Consent to be randomised into the proposed study

Participant type(s)

Patient

Age group

Adult

Sex

Male

Target number of participants

600

Key exclusion criteria

1. Increased serum alphafetoprotein (AFP) (but not human chorionic gonadotropin [HCG]) preorchidectomy
2. Coexistent or previously treated malignant disease or other condition or factor preventing adherence to the study schedule and follow-up

Date of first enrolment

03/01/1995

Date of final enrolment

03/01/1998

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

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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****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		20/02/2005		Yes	No
Other publications		20/09/2005		Yes	No