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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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 28/02/2001	**Overall study status** Completed	
Last Edited 20/12/2007	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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.

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

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

Key secondary outcome(s)
Impact of dose on acute morbidity and quality of life.

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

Healthy volunteers allowed
No

Age group
Adult

Sex
Male

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
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

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