

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

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

**Contact details**  
MRC Clinical Trials Unit  
222 Euston Road  
London  
United Kingdom  
NW1 2DA

## 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.

### **Study design**

Randomised controlled trial

### **Primary study design**

Interventional

### **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?
<a href="#">Results article</a>		20/02/2005		Yes	No
<a href="#">Other publications</a>		20/09/2005		Yes	No