

# A randomised trial of total prostatectomy versus radiotherapy versus no immediate treatment in early prostate cancer

<b>Submission date</b> 06/04/2000	<b>Recruitment status</b> Stopped	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 06/04/2000	<b>Overall study status</b> Stopped	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 19/09/2017	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## 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

### Protocol serial number

PR06

## Study information

### Scientific Title

A randomised trial of total prostatectomy versus radiotherapy versus no immediate treatment in early prostate cancer

**Study objectives**

To determine whether total prostatectomy or radiotherapy confer benefit in terms of survival or development of metastases over no immediate treatment alone.

**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**

Prostate cancer

**Interventions**

1. The first group receives total prostatectomy
2. The second receive radiotherapy
3. The third receive no immediate treatment

**Intervention Type**

Other

**Phase**

Not Specified

**Primary outcome(s)**

1. Survival time to metastases
2. Morbidity
3. Local recurrence
4. Quality of life
5. Time to progression

**Key secondary outcome(s)**

Not provided at time of registration

**Completion date**

01/06/1996

**Reason abandoned (if study stopped)**

The overall target for recruitment was 1800 patients, but the trial accrued only 35 (mean age 69 years, median PSA level at entry 12 ng/mL). Recruitment was formally halted following the recommendation of the independent Data Monitoring Committee in October 1996.

# Eligibility

## Key inclusion criteria

1. Newly diagnosed, biopsy-proven adenocarcinoma of the prostate
2. Stage T1b/T1c/T2, N0, M0
3. Negative bone scan
4. No previous malignancy (except skin)

## Participant type(s)

Patient

## Healthy volunteers allowed

No

## Age group

Not Specified

## Sex

Male

## Key exclusion criteria

Opposite of inclusion criteria

## Date of first enrolment

01/06/1994

## Date of final enrolment

01/06/1996

# Locations

## Countries of recruitment

United Kingdom

England

Belgium

Switzerland

## Study participating centre

Department of Urology

London

United Kingdom

SW3 6JJ

# 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="#">Other publications</a>	Early closure in reported in 2004	01/12/2004		Yes	No