

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

Submission date 06/04/2000	Recruitment status Stopped	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 06/04/2000	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 19/09/2017	Condition category 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
Mr Robert Shearer

Contact details
Department of Urology
The Royal Marsden
Fullham Road
London
United Kingdom
SW3 6JJ

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Not Specified

Participant information sheet

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 measure

1. Survival time to metastases
2. Morbidity

3. Local recurrence
4. Quality of life
5. Time to progression

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/06/1994

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

Age group

Not Specified

Sex

Male

Target number of participants

1800 planned, 35 recruited at time of early closure in 1996.

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

Belgium

England

Switzerland

United Kingdom

Study participating centre

Department of Urology

London

United Kingdom

SW3 6JJ

Sponsor information

Organisation

Medical Research Council (MRC) (UK)

Sponsor details

20 Park Crescent

London

United Kingdom

W1B 1AL

+44 (0)20 7636 5422

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?
Other publications	Early closure in reported in 2004	01/12/2004		Yes	No