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

Submission date 06/04/2000	**Recruitment status** Stopped	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 06/04/2000	**Overall study status** Stopped	
Last Edited 19/09/2017	**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

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
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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