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A randomised clinical trial of hormones plus radiotherapy vs hormone therapy alone in non-metastatic prostate cancer

Submission date 06/04/2000	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 06/04/2000	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 18/10/2018	**Condition category** Cancer	[_] Individual participant data

Plain English summary of protocol
http://cancerhelp.cancerresearchuk.org/trials/a-trial-looking-at-hormone-therapy-with-or-without-radiotherapy-in-advanced-prostate-cancer

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00002633

Secondary identifying numbers
G9805643 (PR07)

Study information

Scientific Title
A randomised clinical trial of hormones plus radiotherapy vs hormone therapy alone in non-metastatic prostate cancer

Study objectives
To evaluate any possible benefit from the addition of external beam radiation therapy to the treatment of patients with non-metastatic prostate cancer who have not had a radical prostatectomy and are receiving hormonal therapy.

More details can be found at: http://www.ctu.mrc.ac.uk/research_areas/study_details.aspx?s=58

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)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Prostate cancer

Interventions
All patients will receive hormonal manipulation.
Patients are randomised to receive:
1. Additional radiotherapy (65-69Gy/35-37f)
2. No additional radiotherapy

Intervention Type
Mixed

Primary outcome measure
Overall survival

Secondary outcome measures
1. Time to disease progression
2. Symptomatic local control measured by the rates of surgical interventions necessary for symptomatic local disease (I.e. the combined incidences of TURPs, stent insertions, nephrostomies and colostomies)
3. Quality of Life measured by the FACT-P questionnaire

Overall study start date
01/06/1999

Completion date
31/08/2005

Eligibility

Key inclusion criteria
1. Histological diagnosis of adenocarcinoma of the prostate within 6 months of randomisation
2. Either (a) clinical stage T3 or T4, NO or NX, MO or (b) clinical stage T2, NO or NX, MO with Prostate-Specific Antigen (PSA) greater than 40 or (c) clinical stage T2, NO or NX, MO with PSA greater than 20 and Gleason sum score greater than or equal to 8
3. The patient must have a bone scan (with X-rays of any areas of abnormal uptake) reported as being free of evidence of bony metastases within 16 weeks prior to randomisation (if not already on hormones) or 16 weeks prior to the start of hormones (if on hormones already)
4. No previous treatment for prostate cancer apart from transurethral resection. However, the patient may have received prior hormone therapy during the 12 weeks prior to randomisation, provided that (a) a negative bone scan was demonstrated, preferably within the 16 weeks prior to starting hormone therapy but certainly within 2 weeks after starting hormone therapy and (b) baseline PSA within 4 weeks prior to hormone therapy is available
5. Eastern Cooperative Oncology Group (ECOG) performance status 0-2
6. Patients must be less than 80 years old
7. Written informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Male

Target number of participants
1,200

Key exclusion criteria
1. A history of previous or concurrent malignancy other than non-melanomatous skin cancer within 5 years of diagnosis of the prostatic cancer.
2. The presence of small-cell or transitional-cell carcinoma in the biopsy specimen.
3. Any contraindication to pelvic radiotherapy (e.g. inflammatory bowel disease).
4. Any serious non-malignant disease resulting in a life expectancy of less than 5 years.

Date of first enrolment
01/06/1999

Date of final enrolment
31/08/2005

Locations

Countries of recruitment
England

United Kingdom

United States of America

Study participating centre
MRC Clinical Trials Unit
London
United Kingdom
NW1 2DA

Sponsor information

Organisation
Medical Research Council (MRC) Clinical Trials Unit - Cancer Division (UK)

Sponsor details
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Sponsor type
Research council

Website

http://www.ctu.mrc.ac.uk/

ROR
https://ror.org/03x94j517

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?
Plain English results				No	Yes
Protocol article	protocol	01/11/2000		Yes	No
Other publications	appraisal results	01/06/2005		Yes	No

Results article	results	17/12/2011	Yes	No
Results article		01/07/2015	Yes	No