

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 ☒ Protocol
Registration date 06/04/2000	Overall study status Completed	☐ Statistical analysis plan ☒ 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

Contact name

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Contact details

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Additional identifiers

ClinicalTrials.gov (NCT)

NCT00002633

Protocol serial number

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.

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

Overall survival

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Male

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

United Kingdom

England

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)

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, 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?
Results article	results	17/12/2011		Yes	No
Results article	results	01/07/2015		Yes	No
Protocol article	protocol	01/11/2000		Yes	No
Other publications	appraisal	01/06/2005		Yes	No
Plain English results				No	Yes