

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

<b>Submission date</b> 06/04/2000	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 06/04/2000	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 18/10/2018	<b>Condition category</b> Cancer	<input type="checkbox"/> 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

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](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**

222 Euston Road

London

United Kingdom

NW1 2DA

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abc@email.com

**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?
<a href="#">Plain English results</a>				No	Yes
<a href="#">Protocol article</a>	protocol	01/11/2000		Yes	No
<a href="#">Other publications</a>	appraisal results	01/06/2005		Yes	No

<a href="#">Results article</a>		17/12/2011	Yes	No
<a href="#">Results article</a>	results	01/07/2015	Yes	No