

# Randomised trial of interstitial brachytherapy as a component of radical radiotherapy for localised prostatic carcinoma

<b>Submission date</b> 23/01/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 23/01/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 29/10/2021	<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-external-radiotherapy-with-or-without-internal-radiotherapy-for-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

## Secondary identifying numbers

RDC00707

# Study information

### Scientific Title

Randomised trial of interstitial brachytherapy as a component of radical radiotherapy for localised prostatic carcinoma

### Study objectives

Interstitial brachytherapy provides a means of delivering high dose radiation accurately localised by radio-active sources placed directly within a tumour. New techniques, in particular transrectal ultrasound allow this to be performed accurately within the prostate gland. It is not clear whether this improves the results over conventional external beam treatment alone and this randomised comparative trial is underway to assess this.

### 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

Standard external beam radiotherapy 55 Gy (control) versus external beam 34 Gy plus brachytherapy 17 Gy

### Intervention Type

Other

**Phase**

Not Specified

**Primary outcome measure**

1. An improvement in local control for prostatic carcinoma as defined by:
  - a. PSA response
  - b. Changes on digital rectal examination
  - c. Local symptom-free duration
  - d. Quality of Life (FACT-P)
2. Prolonged disease specific survival consequent upon the improved local survival
3. Reduced bowel morbidity because of the more localised nature of the interstitial component of the radiation dose delivered

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

07/07/1997

**Completion date**

07/07/2004

**Eligibility****Key inclusion criteria**

Patients with prostatic carcinoma who after routine staging have no evidence of distant metastasis. Patients will be male and over 40 years of age. In general external beam treatment is delivered as an outpatient whilst the interstitial treatment will require two to three days inpatient care.

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Male

**Target number of participants**

Not provided at time of registration

**Total final enrolment**

218

**Key exclusion criteria**

1. Prostate specific antigen (PSA) over 50
2. Previous Transurethral Resection of the Prostate (TURP)
3. Radiological evidence of distant metastasis

**Date of first enrolment**

07/07/1997

**Date of final enrolment**

07/07/2004

## Locations

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Marie Curie Research Wing**

Northwood

United Kingdom

HA6 2RN

## Sponsor information

**Organisation**

NHS R&D Regional Programme Register - Department of Health (UK)

**Sponsor details**

The Department of Health

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

+44 (0)20 7307 2622

dhmail@doh.gsi.org.uk

**Sponsor type**

Government

**Website**

<http://www.doh.gov.uk>

## Funder(s)

**Funder type**

Government

## Funder Name

NHS Executive London (UK)

## Results and Publications

### Publication and dissemination plan

Not provided at time of registration

### Intention to publish date

### Individual participant data (IPD) sharing plan

Not provided at time of registration

### 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="#">Results article</a>	results	01/05/2012		Yes	No
<a href="#">Results article</a>	results	01/08/2019	08/05/2019	Yes	No
<a href="#">Plain English results</a>		31/08/2005	29/10/2021	No	Yes