

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

Submission date 23/01/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 23/01/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 29/10/2021	Condition category 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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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?
Results article	results	01/05/2012		Yes	No
Results article	results	01/08/2019	08/05/2019	Yes	No
Plain English results		31/08/2005	29/10/2021	No	Yes