ISRCTN98241100 https://doi.org/10.1186/ISRCTN98241100

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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 23/01/2004	**Overall study status** Completed	
Last Edited 29/10/2021	**Condition category** Cancer	

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
Dr Peter Hoskin

Contact details
Marie Curie Research Wing
Mount Vernon Hospital
Rickmansworth Road
Northwood
United Kingdom
HA6 2RN
+44 (0)1923 826111
a@b.com

Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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(s)
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

Key secondary outcome(s))

Not provided at time of registration

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

Healthy volunteers allowed
No

Age group
Adult

Sex
Male

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
United Kingdom

England

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)

Funder(s)

Funder type
Government

Funder Name
NHS Executive London (UK)

Results and Publications

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