Gold seed markers for improved set-up accuracy during high dose radiotherapy for prostate cancer

Submission date	Recruitment status	[] Pros
30/09/2004	No longer recruiting	[] Prol
Registration date	Overall study status	[] Stat
30/09/2004	Completed	[] Res
Last Edited	Condition category	[_] Indi
15/04/2016	Cancer	[] Rec

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s) Scientific

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

- spectively registered
- tocol

istical analysis plan

- ults
- vidual participant data
- ord updated in last year

N0067124367

Study information

Scientific Title

Gold seed markers for improved set-up accuracy during high dose radiotherapy for prostate cancer

Study objectives

To assess the impact on set-up accuracy of 4 methods of preparing the patient's bladder and rectum before radiotherapy, using gold seed markers for reference

Ethics approval required Old ethics approval format

Ethics approval(s)

Granted by Wirral Local Research Ethics Committee (UK) on 16/04/2003, reference number 33 /03.

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

Health condition(s) or problem(s) studied Cancer: Prostate

Interventions

Clinical trial
Randomised trial
Randomised trial
Full bladder, empty rectum
Full bladder, full rectum
Empty bladder, full rectum

Intervention Type Other

Phase

Not Specified

Primary outcome measure

Prior to July 2008:

- 1. Prostate position and movement
- 2. Radiation dose to tumour and normal tissues
- 3. Toxicity
- 4. Quality of life
- 5. Biochemical relapse free survival
- 6. Overall survival

Modified on 23 July 2008 - primary end points as follows:

1. Determination of magnitude of set-up errors in radiotherapy of prostate cancer using current and alternative set-up procedures

- 2. Early and late treatment toxicity
- 3. Biochemical (PSA) relapse free survival

4. Overall survival will also be recorded, but the study is not large enough to detect any

difference between the groups

Secondary outcome measures

Not provided at time of registration

Overall study start date

21/05/2003

Completion date

11/11/2005

Eligibility

Key inclusion criteria Patients with prostate cancer undergoing radiotherapy.

Added 29 July 2008:

1. Histologically confirmed, previously untreated, locally confined adenocarcinoma of the prostate (T1-T3a, NO, MO)

- 2. PSA <50NG/ML prior t any hormone therapy
- 3. No other malignancy within the previous 5 years
- 4. No indwelling urinary catheter
- 5. The use of neoadjuvant hormone therapy is permitted, but not mandatory

Participant type(s)

Patient

Age group Not Specified

Sex Male **Target number of participants** Total target recruitment = 48 patients

Key exclusion criteria Not provided at time of registration

Date of first enrolment 21/05/2003

Date of final enrolment 11/11/2005

Locations

Countries of recruitment England

United Kingdom

Study participating centre Clatterbridge Centre for Oncology Wirral United Kingdom CH63 4JY

Sponsor information

Organisation Department of Health

Sponsor details

Richmond House 79 Whitehall London United Kingdom SW1A 2NL

Sponsor type Government

Website http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type Government

Funder Name Clatterbridge Centre for Oncology NHS Trust (UK)

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