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

Submission date 30/09/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 30/09/2004	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 15/04/2016	**Condition category** Cancer	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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
1. Clinical trial
2. Randomised trial
2.1 Full bladder, empty rectum
2.2 Full bladder, full rectum
2.3 Empty bladder, empty rectum
2.4 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