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

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

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

Dr Isabel Syndikus

#### Contact details

Clatterbridge Centre for Oncology Clatterbridge Road Bebington Wirral United Kingdom CH63 4JY +44 (0)151 334 1155 isabel.syndikus@ccotrust.nhs.uk

# Additional identifiers

Protocol serial number 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

# Study type(s)

Treatment

### 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(s)

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

#### Key secondary outcome(s))

Not provided at time of registration

#### 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** 

# Healthy volunteers allowed

No

#### Age group

**Not Specified** 

#### Sex

Male

#### 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

United Kingdom

# England

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

# Sponsor information

## Organisation

Department of Health

# Funder(s)

# Funder type

Government

#### **Funder Name**

Clatterbridge Centre for Oncology NHS Trust (UK)

# **Results and Publications**

Individual participant data (IPD) sharing plan

# IPD sharing plan summary

Not provided at time of registration