ISRCTN05909154 https://doi.org/10.1186/ISRCTN05909154

SEED 02 - Evaluation of Image Guided Radiotherapy Techniques for Prostate Radiotherapy

Submission date	Recruitment status	[_] Prospectively registered
28/09/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
28/09/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
02/02/2016	Cancer	

Plain English summary of protocol

Background and study aims
Prostate cancer is the most common cancer in men in the UK. High-dose radiotherapy treatment involves using a defined dose of radiation to kill the cancerous cells in the prostate. The standard schedule uses 32 – 37 treatments over 7-8 weeks. The treatment is more likely to be successful if the entire prostate receives radiation every time. However, the prostate moves about 5mm between treatments, mostly because of different rectal and bladder filling. The safety margin around the prostate is small, only 5mm. If you increase the safety margin, side effects become more common. Small gold seeds are implanted as prostate reference markers and help to correct shifts during treatment. The aim of this study is to compare different ways of taking images of the prostate and its position during radiotherapy treatment. Daily 'on-line' kilo-voltage imaging will be compared to the current set-up 'off-line' mega-voltage imaging. The new kilo-voltage imaging system uses less radiation and gives clearer pictures. This makes daily correction of patient position possible. We also want to find out how much benefit can be derived from additional cone beam CT scanning.

Who can participate?
Any man undergoing radical radiotherapy for localized prostate cancer.

What does the study involve?
All participants have three gold seeds implanted into their prostate gland. The procedure takes about 10 minutes. Two or three weeks after the insertion of the gold seeds, participants attend for a CT scan which will take pictures of the pelvic tissues and bones. The radiographer makes three tiny permanent marks on the patient's skin. The doctor and radiographers use the information from the scan to produce a treatment plan. Participants are randomly allocated to one of two groups, one group having kilo-voltage imaging and the other having mega-voltage imaging. The radiographers ensure that the patient is in the correct position before treatment. At each of the first three treatments, pictures are taken on the treatment machine and during the first week, one cone beam CT scan. For the rest of their treatment patients have a weekly

cone beam CT scan and then either daily kilo-voltage images or weekly mega-voltage images as allocated. A month after finishing treatment patients see the research nurse and doctor. Patients then have checkups after 6, 12, 18 and 24 months.

What are the possible benefits and risks of participating?
We do not yet know whether there will be any benefits to using the new imaging techniques. However, the following are possible benefits that we think may apply. We will be able to deliver treatment more accurately and therefore make it more effective. The knowledge gained will also benefit other patients in the future. Patients will be exposed to additional small amount of radiation from the cone beam CT scans similar to the amount received from a normal CT scan. Radiation can cause second cancers many years after treatment. This effect has never been consistently proven for men who receive radiotherapy as part of their treatment. It is not possible to be sure how much, if at all the additional imaging exposure will add to it. Considering the patient's age and the amount of radiation therapy, we do not think there are significant additional risks to your health. Patients in the kilo-voltage imaging group have daily treatment pictures using the much lower energy kilo-voltage x-rays. The overall amount of radiation given from the imaging pictures is on average less than for the mega-voltage group. It is difficult to be exact about it in advance as some patients require more imaging than others.

Where is the study run from?
Clatterbridge Centre for Oncology (UK)

When is the study starting and how long is it expected to run for?
August 2006 to December 2009

Who is funding the study?
Clatterbridge Centre for Oncology (UK)

Who is the main contact?
Dr Isabel Syndikus
isabel.syndikus@ccotrust.nhs.uk

Contact information

Type(s)
Scientific

Contact name
Dr Isabel Syndikus

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

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0067189218

Study information

Scientific Title
SEED 02 - Evaluation of Image Guided Radiotherapy Techniques for Prostate Radiotherapy

Study objectives
To compare different ways of taking images of the prostate and its position during radiotherapy treatment (high energy x-rays beams). Daily 'on line' kilo voltage imaging will be compared to 'off-line mega voltage imaging' and a standard imaging protocol. This is known as Image Guided Radiotherapy or IGRT.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Central Manchester Local Research Ethics Committee approved protocol version 2 30/05/2006 and amendment Number 1 Version 3 18/01/2007, ref 06/Q1407/32

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
Cancer: Prostate

Interventions
Patients will have small gold seeds implanted into the prostate under local anaesthetic. Radiotherapy treatment planned as normal then randomised to be imaged by either:
1. Retrospective 'off-line' mega voltage imaging (standard technique)
2. Daily 'on line' kilo voltage imaging (newer technique)
for the 7- 8 weeks of radiotherapy. In both arms, the seed markers are used for treatment verification.
Additionally patients undergo a cone beam CT weekly prior to treatment. One follow-up visit approximately 1 month after completion of radiotherapy, then normal follow-up.

The study will assess the current verification methods available (Daily 'on line' kilovolt age imaging, 'off-line' mega voltage cancer) The different technologies will be directly compared in this randomised controlled trial. All eligible patients will be consented, and will then have small gold seeds implanted into the prostate under local anaesthetic. Approximately 2-3 weeks later they will attend the radiotherapy centre and have their treatment planned as normal. This involves having scans taken and having small tattoos marked on their skin. After the CT planning scan, patients will be randomised to be imaged by either:
A: Retrospective 'off-line' mega voltage imaging (standard technique)
B: Daily 'on line' kilovolt age imaging (newer technique) during the 7-8 weeks of their radiotherapy

During treatment, the patient is positioned on the treatment couch as per standard protocol. In both arms, the seed markers are used for treatment verification. The mega voltage imaging is performed according to the standard imaging protocol. Other images, known as orthogonal EPID images of the treatment fields (the area being treated) are taken daily. These images will only be used later to compare daily variation in seed position. Kilovolt age images are taken every day prior to treatment and the patient will be repositioned as needed daily as per standard protocol. After the correction and directly before the treatment commences, mega voltage images of each field are recorded in the same way as in the other arm. Additionally patients undergo a cone beam CT weekly prior to the treatment.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Mean total displacement in tumour bed centre of gravity during a course of radiotherapy in both treatment arms

Secondary outcome measures
1. Mean daily displacement in tumour bed centre of gravity expressed as 3D co-ordinates
2. Intra- and inter-observer variability in marker localisation
3. Tolerance level of positional correction
4. Production of an on line image correction protocol

Overall study start date
11/08/2006

Completion date
31/12/2009

Eligibility

Key inclusion criteria
1. Histological confirmed, previously untreated, locally confined adenocarcinoma of the prostate (T1-T3a, N0, M0)
2. PSA <50ng/ml prior to any hormone therapy
3. Suitable and fit for radical conformal therapy or intensity-modulated radiotherapy

Participant type(s)
Patient

Age group
Adult

Sex
Male

Target number of participants
48, 24 in each arm.

Key exclusion criteria
1. Other stages of prostate cancer than T1-T3a, N0, M0 as these may indicate different treatment
2. Patients not suitable for radiotherapy
3. Other malignancy within the previous 5 years (as they may have had treatment that will interfere with this study)
4. Indwelling urinary catheter
5. No total hip replacement (as this affects the imaging scanner).

Date of first enrolment
11/08/2006

Date of final enrolment
31/12/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Clatterbridge Centre for Oncology
Merseyside
United Kingdom
CH63 4JY

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2007 Update - 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
Not defined

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2011		Yes	No