ISRCTN15849938 https://doi.org/10.1186/ISRCTN15849938

Which correction protocol gives the lowest cumulative rectal dose in prostate cancer patients who are treated with external beam radiotherapy? A phase II modelling study

Submission date
26/02/2007

Recruitment status
No longer recruiting

Registration date
26/02/2007

Overall study status
Completed

Last Edited
22/09/2021

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr M A D Haverkort

Contact details
Academisch Medisch Centrum
Afdeling Radiotherapie
Amsterdam
Netherlands
1105 AZ
+31 (0)20 566 3750
m.a.haverkort@amc.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
MEC 06/268, NL865 (NTR879)

Study information

Scientific Title
Which correction protocol gives the lowest cumulative rectal dose in prostate cancer patients who are treated with external beam radiotherapy? A phase II modelling study

Study objectives
To reduce cumulative radiation dose in the rectum in prostate cancer patients who are treated with curative intent using external beam radiotherapy. We will investigate whether position correction based on implanted gold markers or re-planning based on sequential Computed Tomography (CT) scans (adaptive margin strategy) is required instead of standard position correction protocols based on bony anatomy. With this knowledge we intend to develop a new treatment protocol for patients with prostate cancer for our department.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from the local medical ethics committee (Medische Etische Commissie Academisch Medisch Centrum) on the 19th December 2006 (ref: MEC 06/268).

Study design
Prospective phase II modeling study

Primary study design
Interventional

Secondary study design
Single-centre

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
External beam radiotherapy, prostatic neoplasms, rectal toxicity, position verification

Interventions
Before the start of the treatment four gold seeds will be implanted in the prostate of the patients. Treatment consists of external beam radiotherapy (77 - 78 Gy) with curative intent. During radiotherapy the prostate position will be measured daily using Portal Imaging (PI) of the gold seeds and bony anatomy and treatment position corrections will be performed using standard daily offline correction protocols for optimal prostate treatment.

In addition to the standard treatment, a CT scan will be performed every day during the first week and once a week thereafter. After the first week an Adaptive Margin Radiotherapy (AMRT) treatment plan will be made, considering both averaged prostate and rectum positions in the first five scans. The cumulative rectum dose will be computed for the original treatment plan, considering repositioning based on PI for bony anatomy and markers and considering the adaptive margin strategy.

Intervention Type
Other

Phase
Phase II

Primary outcome measure
D30% rectal wall (the minimum dose in 30% of the rectal wall that receives the highest dose) from the cumulative dose-volume-histograms

Secondary outcome measures
1. D10% rectal wall, D50% rectal wall, D70% rectal wall
2. D mean anal canal
3. Crude cost analysis

Overall study start date
01/02/2007

Completion date
01/02/2008

Eligibility

Key inclusion criteria
1. Histologically proven localised (cT1-3) adenocarcinoma of the prostate
2. Primary treatment for the prostate cancer with more than 70 Gy radiotherapy with curative intent
3. World Health Organisation (WHO) performance status zero to two
4. The administration of concomitant hormonal therapy is allowed, however only if started more than six months before radiotherapy to limit the possibility of shrinkage of the prostate during the course of radiotherapy
5. Be able to lie in lithotomy position
6. Meet all Magnetic Resonance Imaging (MRI) safety criteria

Participant type(s)
Patient

Age group
Not Specified

Sex
Male

Target number of participants
20

Total final enrolment
20

Key exclusion criteria
1. No hip prosthesis
2. No involvement of pelvic lymph node assessed by CT scan or laparoscopic surgery
3. No evidence of distant metastases
4. No Transurethral Resection of the Prostate (TUR-P) in the last three months
5. No anorectal surgery in the past or other situations in which the anorectal anatomy is abnormal
6. No use of anticoagulation therapy (i.e. coumarins or heparins), however the use of anti-platelet therapy is allowed
7. No coagulation disorder

Date of first enrolment
01/02/2007

Date of final enrolment
01/02/2008

Locations

Countries of recruitment
Netherlands

Study participating centre
Academisch Medisch Centrum
Amsterdam
Netherlands
1105 AZ

Sponsor information

Organisation
Academic Medical Centre (AMC) (The Netherlands)

Sponsor details
Department of Radiotherapy
P.O. Box 22660
Amsterdam
Netherlands
1100 DD

Sponsor type
Hospital/treatment centre

Website
http://www.amc.uva.nl/

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Academic Medical Centre (AMC) (The Netherlands)

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		01/06/2011	22/09/2021	Yes	No