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

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24967

Source
NTR

Brief title
Position correction to lower rectal dose

Health condition

Rectum toxicity is the most important dose-limiting factor for radiotherapy of the prostate. As the trends towards dose escalation continue, margins are diminished and radiotherapy delivery starts to be adapted to the position variation of the prostate. An often used strategy is to correct for the position of the prostate based on implanted markers. Another way of correcting for the prostate movement is AMRT (adaptive margin radiotherapy). However for both methods little is known about its implications for the undesired radiation dose at the rectal wall.

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Afdeling Radiotherapie B-0
Meibergdreef 9

1105 AZ Amsterdam
Nederland
0031-20-5663750
0031-20-6091278
Source(s) of monetary or material Support: none

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

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

Study description

Background summary

A prospective phase II modeling study will be undertaken to determine the cumulative radiation dose in the rectum. A position correction protocol based on implanted gold seeds and an adaptive margin strategy based on prostate and rectum delineation on sequential CT scans with the standard position correction based on bony anatomy will be compared. Twenty consecutive prostate cancer patients without metastasis who have given informed consent will be included. Before the start of the treatment 4 gold seeds will be implanted in the prostate of the patients. Treatment consists of external beam radiotherapy (77-78Gy) 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 5 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. These results will indicate if PI position verification on markers is sufficient to achieve adequate rectum sparing, or whether an additional re-planning based on adaptive margin strategy is required.

Study objective

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 CT scans (adaptive margin strategy) is required in stead of to 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.

Intervention

11 CT scans
Patients will be treated according to standard care with high dose intensity modulated radiotherapy and gold marker based position correction. Furthermore they will undergo CT scans in treatment position daily during the first week and weekly thereafter.
These data will be used to do modelling for the three correction arms.

Contacts

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Eligibility criteria

Inclusion criteria

Histologically proven localized (cT1-3) adenocarcinoma of the prostate
1. Primary treatment for the prostate cancer with more than 70 Gy radiotherapy with curative intent;
2. WHO performance status 0-2;
3. The administration of concomitant hormonal therapy is allowed, however only if started more than 6 months before radiotherapy to limit the possibility of shrinkage of the prostate during the course of radiotherapy;
4. Be able to lie in lithotomy position;
5. Meet all MRI safety criteria.

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 TUR-P in the last 3 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. coumarines or heparins), however the use of anti-platelet therapy is allowed;
7. No coagulation disorder.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2007
Enrollment:	20

Type:	Anticipated

Ethics review

Positive opinion
Date: 24-01-2007

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL865
NTR-old	NTR879
Other	: MEC 06/268
ISRCTN	ISRCTN15849938

Study results

Summary results
N/A