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

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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…

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24967

Bron
NTR

Verkorte titel
Position correction to lower rectal dose

Aandoening

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.

Ondersteuning

Primaire sponsor: Academisch Medisch Centrum
Afdeling Radiotherapie B-0
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Nederland
0031-20-5663750
0031-20-6091278
Overige ondersteuning: none

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-02-2007
Aantal proefpersonen:	20
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	24-01-2007
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten

N/A