Quantification and technique development to reduce ano-rectal toxicity in prostate radiotherapy.

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To objectify and quantify patients ano-rectal complaints to identify the exact pathophysiology and involved anatomic structures. Following this, irradiation techniques can be developed or modified to selectively spare the abovementioned structures,...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Reproductive and genitourinary neoplasms gender unspecified NEC
Study type	Observational invasive

Summary

ID

NL-OMON33176

Source
ToetsingOnline

Brief title
Quantification and reduction of anorectal toxicity in prostate radiotherapy

Condition

- Reproductive and genitourinary neoplasms gender unspecified NEC
- Prostatic disorders (excl infections and inflammations)

Synonym
prostate cancer, prostate carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Koninging Wilhelmina Fonds

Intervention

Keyword: anorectal toxicity, prostate, radiotherapy

Outcome measures

Primary outcome

Subjective complaints, based on questionnaires.

Anal pressures and rectal compliance.

Amount and severity of telangiectasias to the rectal and sigmoid mucosa.

In addition, the course of these parameters over 2 years and their correlation,

and the correlation to the doses to the rectum and anal canal.

Secondary outcome

Not applicable.

Study description

Background summary

Prostate cancer has an incidence of 8500/year in The Netherlands. One of the curative treatment modalities, external beam radiotherapy (EBRT), has a significant dose-response relationship. However, toxicity to surrounding tissues is limiting dose-escalation. Especially ano-rectal toxicity has a serious impact on patients quality of life. Given the high curation rates (and long survival) of EBRT in localized prostate cancer, late toxicity is an important issue.
Several reports have been made about relationships between the incidence and severity of ano-rectal complaints and the radiation dose to the rectum and anal canal. This means that lowering the dose to these organs reduces the risk of ano-rectal toxicity. Modern EBRT techniques aim at high conformality, thereby enabling the radiation oncologist to give a high dose to the target volume, while selectively sparing the surrounding normal tissues. In the UMCN several modalities are used to achieve this goal, like intensity-modulated radiotherapy (IMRT), implantation of fiducial markers for postion verification and -correction, and fusion of CT and MRI images for an optimal target volume

delineation. By applying these techniques, uncertainty margins are kept as small as possible, thus keeping the volume of irradiated normal tissues as low as possible. In addition, daily inserted endorectal balloons are used to spare the rectal wall.
However, to further reduce the ano-rectal toxicity rates, it is important to identify the exact pathophysiology and specific anatomic structures, involved in its development to eventually modify irradiation techniques and selectively spare these structures.
The first step in this proces is to objectify patients complaints by anorectal manometry (to measure pressures in the anal canal, and compliance and sensibility of the rectum) and rectosigmoidoscopy (to evaluate mucosal damage).

Study objective

To objectify and quantify patients ano-rectal complaints to identify the exact pathophysiology and involved anatomic structures.
Following this, irradiation techniques can be developed or modified to selectively spare the abovementioned structures, thereby reducing the ano-rectal toxicity rate in prostate EBRT.

Study design

Cohort study, following patients from baseline (i.e. before radiotherapy) to 2 years after treatment. Follow-up with questionnaires, ano-rectal manometries, and rectosigmoidoscopies will be performed. Eventually, these data will be correlated to subjective complaints and to the dose to specific anatomic structures.

Study burden and risks

During a follow-up time of 2 years, patients are asked to fill out a questionnaire (EPIC) five times at regular appointments on the outpatient clinic, which will take approximately 10 minutes of their time.

In addition, in these 2 years 4 ano-rectal manometries will be performed (baseline, and 6, 12, and 24 months post-radiotherapy, respectively). Each investigation will take approximately 1 hour of time. Complications are very rare; in literature some cases of rectal blood loss in patients with pre-existing ulcerative colitis, and a rectal rupture in a patient with previous rectal surgery are reported.

Six months, 12 months, and 24 months post-radiotherapy a rectosigmoidoscopy will be done, taking 5-20 minutes of time. The complication rate of this investigation is very low (0.14-0.25%) and consists of perforation. The mortality rate of rectosigmoidoscopies alone is unknown. However, for

colonoscopies in general this is < 0.02%

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Biopsy proven prostate carcinoma.
Localized prostate carcinoma (cT1-3N0M0)
Written informed consent.

Exclusion criteria

Previous treatment for this tumour, other than neo-adjuvant androgen suppression therapy.

Distant metastases
Contra-indications for radiotherapy (Morbus Crohn, ulcerative colitis, severe diverticulitis.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	17-08-2009
Enrollment:	60
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	06-07-2009
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
CCMO	NL26486.091.09