SEMINAL VESICLE MOTION RELATIVE TO THE PROSTATE

Published: 17-07-2006
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To quantify the motion of the seminal vesicles.

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

Summary

ID

NL-OMON30118

Source
ToetsingOnline

Brief title
SEMOP

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: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: motion, prostate cancer, seminal vesicles

Outcome measures

Primary outcome

Quantification of the seminal vesicle motion relative to the prostate.

Secondary outcome

none

Study description

Background summary

The clinical target volume (CTV) is a tissue volume that contains a demonstrable extent and location of the malignant growth and/or subclinical microscopic malignant disease, which have to be eliminated. To account for uncertainties regarding movement of the CTV, variation in shape and size of the CTV and variations in beam geometry characteristics, a margin is added to the CTV. The planning target volume (PTV) is the CTV plus this margin. Use of fudicial markers, especially with on-line position verification, will reduce geometrical uncertainties. This will make it possible to use a smaller margin, resulting in a lower radiation dose delivered to normal tissue surrounding the CTV. For a prostate cancer patient with a risk of involvement of the seminal vesicles the CTV contains the prostate and seminal vesicles.
The fiducial markers are only implanted in the prostate and corrections for translation and in future also rotation will be based on the position of the fiducial markers in the prostate. Although there are studies reporting about shape variation of the prostate and seminal vesicles, only a few studies used repeat CT scans in combination with fiducial markers. Because the prostate shape has rounded edges, rotations of the prostate relative to the seminal vesicles cannot be assessed in a precise manner by means of repeat CT scans without fiducial markers. Using fiducial markers in combination with repeat CT scans will allow a much more precise assessment of the motion of the seminal vesicles relative to the prostate. For the use of an off-line or on-line treatment verification protocol based on intraprostatic fiducial markers, this data is required to determine the minimal margin that can be used for the seminal vesicles. Until now there is no study providing sufficient data to determine this minimal margin.

Study objective

To quantify the motion of the seminal vesicles.

Study design

Twenty patients will be included in this study. A week after implantation of 4 fiducial markers the planning CT scan will be made. During the period of radiotherapy 3 additional CT scans will be made for each patient, in week 2, 4 and 6 of treatment. The prostate, fiducial markes and seminal vesicles will be outlined on each CT scan. The difference in position of the seminal vesicles relative to the fiducial markers and prostate will be determined.

Study burden and risks

Three additional CT scans will be made. This will take about 10 minute per CT scan. The aim is to plan de CT scans directly before or after the treatment of that day.
The additional CT scans will increase the effective radiation dose, but this an insignifcant increase compared to the radiation dose received by the small pelvis.

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

Patients who will be treated with external beam radiotherapy for prostate cancer.

Exclusion criteria

None

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	27-07-2006
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	17-07-2006
Application type:	First submission

Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL12368.078.06