Contrast enhanced ultrasound imaging to support prostate cancer brachytherapy treatment and follow up after treatment.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON22373

Source
Nationaal Trial Register

Brief title
CEUS to support and follow up prostate cancer brachytherapy

Health condition

Prostate and cancer.

Sponsors and support

Primary sponsor: Academic Medical Centre Amsterdam, department of urology and department of radiotherapy

Intervention

Outcome measures

Primary outcome

Can contrast enhanced ultrasound be used for the detection of prostate lesions suspicious for cancer that can be used for brachytherapy dose adjustment.

Secondary outcome

Can contrast enhanced ultrasound of the prostate be used to follow up suspicious lesions of the prostate in prostate cancer patients after brachytherapy.

Study description

Background summary

Brachytherapy is globally used as a primary treatment for prostate cancer. The advantage of brachytherapy is that the radiation dose on healthy organs can be limited. Because prostate cancer is a multifocal disease the whole prostate has to be irradiated. With the introduction of 3-dimensional radiotherapy it became possible to treat the prostate gland to high doses without increasing toxicity. In this study new treatment techniques are being used to increase the radiation dose on those places where cancer existence is suspected based on contrast enhanced ultrasound imaging.
Afetr brachytherapy patients will undergo 3 contrast enhanced ultrasound investigations on determined moments in time to follow up suspicious lesions

Study objective

Brachytherapy is globally used as a primary treatment for prostate cancer. The advantage of brachytherapy is that the radiation dose on healthy organs can be limited. Because prostate cancer is a multifocal disease the whole prostate has to be irradiated. With the introduction of 3-dimensional radiotherapy it became possible to treat the prostate gland to high doses without increasing toxicity. In this study new treatment techniques are being used to increase the radiation dose on those places where cancer existence is suspected based on contrast enhanced ultrasound imaging. By increasing the radiation dose on areas suspicious of cancer oncological outcomes should improve.

Suspicious lesions found with contrast enhanced ultrasound should decrease or disappear during the following up of patients after brachytherapy.

Study design

baseline before EBRT, baseline before brachytherapy, 2 weeks after, 3 months after, 6 months after.

Intervention

Patients will undergo a total of 5 transrectal contrast enhanced ultrasound investigations of the prostate before and after standard brachytherapy treatment. To administer the contrast agent, patients will receive an intravenous infusion line.

Contacts

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Eligibility criteria

Inclusion criteria

1. Histologically proven adenocarcinoma of the prostate;

2. Patients treated by external beam radiotherapy followed by a pulsed dose-rate (PDR) brachytherapy boost;

3. Age ¡Ü 80 years;

4. WHO performance status ¡Ü 2 (appendix B);

5. International Prostate Symptom Score (IPSS) ¡Ü 20 (appendix C);

6. Maximal urinary flow ¡Ý 10 ml/sec;

7. Postvoiding residual bladder volume ¡Ü 200 ml;

8. Prostate volume on trans rectal ultrasound ¡Ü 60 ml;

9. No inflammatory bowel diseases such as colitis ulcerosa or M. Crohn;

10. No metallic hip prosthesis;

11. No TURP within 6 months before radiation treatment;

12. No co-morbidity not allowing general or spinal anesthesia;

13. No cardiac diseases:

a. Coronary ischemic hart disease;

b. Coronary artery intervention in the last year;

c. Acute or class III/IV cardiac failure;

d. Severe heart arrhythmia;

e. Right-to-left shunt;

f. Pulmonary hypertension (pulmonary artery pressure > 90 mmHg);

14. No uncontrolled systemic hypertension;

15. No adult respiratory distress syndrome;

16. No prior radiotherapy on prostate or pelvic area;

17. Possible to comply with follow-up;

18. Written informed consent.

Exclusion criteria

See inclusion criteria.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	N/A: single arm study

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-11-2007
Enrollment:	10
Type:	Anticipated

Ethics review

Positive opinion

Date:	13-12-2007
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	NL663
NTR-old	NTR1168
Other	: incomplete
ISRCTN	Wordt niet aangevraagd/Observational study

Study results

Summary results

N/A