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

Gepubliceerd: 13-12-2007 Laatst bijgewerkt: 18-08-2022

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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON22373

Bron
Nationaal Trial Register

Verkorte titel
CEUS to support and follow up prostate cancer brachytherapy

Aandoening

Prostate and cancer.

Ondersteuning

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

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

See inclusion criteria.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-11-2007
Aantal proefpersonen:	10
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	13-12-2007
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	NL663
NTR-old	NTR1168

Register	ID
Ander register	: incomplete
ISRCTN	Wordt niet aangevraagd/Observational study

Resultaten

Samenvatting resultaten
N/A