PSMA vs. FDHT PET/CT for restaging recurrent prostate cancer

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Studies on PSMA PET/CT the past few years are promising but often of retrospective nature and with heterogeneous patient populations. In our academic centre there are currently two trials running with 18 F-FDHT PET/CT. Results are promising, but…

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23616

Bron
NTR

Verkorte titel
PaFe

Aandoening

Biochemical recurrent Prostate Cancer, post-radiotherapy, functional imaging.
Biochemisch recidief prostaatkanker, na radiotherapie, functionele beeldvorming

Ondersteuning

Primaire sponsor: University Medical Center Groningen
Overige ondersteuning: department of urology, UMCG, head of department: prof.dr. I.J. de Jong

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Main study parameter/endpoints
- Visual assessment of number of lesions en conclusion of re-staging (localized disease, systemic disease or a combination of the two) according to 68 Ga-PMSA PET/CT and 18 F-FDHT PET/CT on patient-by-patient basis.
- Semi-quantitative lesion by lesion comparison of tracers by measuring and evaluating the maximum and mean standardized uptake value (SUVmax , SUVmean)

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Recurrent prostate cancer occurs often and is preceded by a rise in PSA (prostate specific antigen). If the rise is more than 2 ng/mL above nadir, this is defined as a biochemical Recurrence (BCR). BCR precedes clinical evident recurrence by years. Restaging with imaging methods is necessary to determine the localisation of recurrence and the adequate treatment. Current restaging is performed with 11 C-choline PET/CT, but has a moderate sensitivity rate and is least accurate in low PSA ranges, while that is exactly the range in which salvage treatment was shown to be most effective. Studies on PSMA PET/CT the past few years are promising but often of retrospective nature and with heterogeneous patient populations. In our academic centre there are currently two trials running with 18 F-FDHT PET/CT. Results are promising, but more research is needed to determine exact value of both PET/CT scans.

Objective: to compare the value (i.e. detection rate) of 68 Ga-PMSA PET/CT with 18 F-FDHT PET/CT and evaluate the accuracy of both tracers.

Study design: A pilot prospective comparative imaging study. Only one point of measurement, where three scans will take place.

Study population: 20 men with biochemical recurrent prostate cancer after radiotherapy who are candidates for local salvage treatment.

Main study parameters/endpoints:

Primary:

- visual assessment of number of lesions en conclusion of re-staging (localized disease, systemic disease or a combination of the two) according to 68 Ga-PMSA PET/CT and 18 F-

FDHT PET/CT on patient-by-patient basis.

- Semi-quantitative lesion by lesion comparison of tracers by measuring and evaluating the maximum and mean standardized uptake value (SUVmax , SUVmean)

Secondary:

Lesion-based analysis by comparing the detected lesions in different sites of recurrence/metastases with lesions detected by mMRI and information from follow-up (PSA response to salvage therapy, confirmative biopsy or lymph node dissection and other imaging studies (X-ray, bone scans)). To assess overall accuracy, sensitivity, specificity, PPV and NPV per imaging modality

Doel van het onderzoek

Studies on PSMA PET/CT the past few years are promising but often of retrospective nature and with heterogeneous patient populations. In our academic centre there are currently two trials running with 18 F-FDHT PET/CT. Results are promising, but more research is needed to determine exact value of both PET/CT scans.

Onderzoeksopzet

1 timepoint, with 2 scans close to each other

Onderzoeksproduct en/of interventie

68Ga-PSMA PET/CT and a 18F-FDHT PET/CT

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

- Histologically proven prostate cancer for which the subject has undergone radiotherapy with curative intent

- Biochemical recurrence according to Phoenix criteria (PSA nadir +2 ng/mL)

- PSA <10 ng/mL

- Written informed consent

- No androgen deprivation therapy in the past 12 months

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Active cancer besides prostate cancer

- Suspected metastases

- PSA > 10 ng/mL

- Androgen deprivation therapy in the past 12 months

- Any contra-indications for undergoing a MRI scan, i.e. metal-containing implants such as pacemaker, defibrillator or wires in the body and metal particles in the eye.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-05-2016
Aantal proefpersonen:	20
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

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	NL5655
NTR-old	NTR5790
Ander register	ABR nr : 56762

Resultaten

Samenvatting resultaten
not applicable