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

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23616

Source
NTR

Brief title
PaFe

Health condition

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

Sponsors and support

Primary sponsor: University Medical Center Groningen
Source(s) of monetary or material Support: department of urology, UMCG, head of department: prof.dr. I.J. de Jong

Intervention

Outcome measures

Primary outcome

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)

Secondary outcome

Secondary study parameters/endpoints

Lesion-based analysis by comparing the number of detected lesions in different sites of recurrence/metastases with PSMA PET/CT and also for FDHT PET/CT 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 the overall accuracy, sensitivity, specificity, PPV (positive predictive value) and NPV (negative predictive value) per imaging modality.

Study description

Background summary

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

Study objective

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.

Study design

1 timepoint, with 2 scans close to each other

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

- 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.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2016
Enrollment:	20
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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	NL5655
NTR-old	NTR5790
Other	ABR nr : 56762

Study results

Summary results
not applicable