FDHT PET/CT for radio-recurrent prostate cancer

No registrations found.

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

Summary

ID

NL-OMON21317

Source
NTR

Brief title
PaFe

Health condition

Prostate cancer
Prostaatkanker

Sponsors and support

Primary sponsor: PI: dr. I.J. de Jong, uroloog. UMCG
Source(s) of monetary or material Support: UMCG

Intervention

Outcome measures

Primary outcome

- visual assessment of number of lesions en conclusion of re-staging (localized disease, systemic disease or a combination of the two) according to 18 F-FDHT PET/CT on patient-by-patient basis.

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

Secondary outcome

Lesion-based analysis by comparing the detected lesions in different sites of recurrence/metastases with lesions detected by standard imaging by mMRI and PSMA PET/CT 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.

Study description

Background summary

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 11C-choline PET/CT or a 68Ga-PSMA PET/CT, Studies on PSMA PET/CT the past few years are very promising and current literature shows that PSMA has a higher detection rate and accuracy than choline in most clinical circumstances (primary vs recurrent and detection of metastases versus local recurrence). 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 the PET tracer scans. We want to assess if this PET tracer can aid in an optimal selection of patients who are eligible for salvage therapy. So no patients undergo invasive treatment, while they have advanced disease, and therefore undergo unnecessary invasive and possible toxic treatment.

Study objective

to assess the detection rate and accuracy of 18 F-FDHT PET/CT and compare to current standard restaging modalities.

Study design

1 meetpunt

Intervention

nvt

Contacts

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Eligibility criteria

Inclusion criteria

A prospective observational imaging pilot study. Only one point of measurement, where one scan will take place.

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

Exclusion criteria

-Anti-androgen treatment in the last 6 months

- other malignancies

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	20-12-2017
Enrollment:	20
Type:	Anticipated

Ethics review

Positive opinion

Date:	17-11-2017
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	NL6663
NTR-old	NTR6841
Other	METc UMCG // EudraCT number // ABR dossiernummer : 2016.208 // 2016-000533-52 // NL56762.042.16

Study results