FDHT PET/CT for radio-recurrent prostate cancer

Gepubliceerd: 17-11-2017 Laatst bijgewerkt: 13-12-2022

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

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

Samenvatting

ID

NL-OMON21317

Bron
NTR

Verkorte titel
PaFe

Aandoening

Prostate cancer
Prostaatkanker

Ondersteuning

Primaire sponsor: PI: dr. I.J. de Jong, uroloog. UMCG
Overige ondersteuning: UMCG

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- 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)

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

1 meetpunt

Onderzoeksproduct en/of interventie

nvt

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

-Anti-androgen treatment in the last 6 months

- other malignancies

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	20-12-2017
Aantal proefpersonen:	20
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

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

Resultaten