

Variation on PSMA Receptor Expression over time in prostate cancer

Gepubliceerd: 03-01-2020 Laatste bijgewerkt: 19-03-2025

We expect that the second measurement will be different from the first measurement by no more than 10%.

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

Samenvatting

ID

NL-OMON24248

Bron

NTR

Verkorte titel

PRET

Aandoening

Prostate cancer

Ondersteuning

Primaire sponsor: None

Overige ondersteuning: This research is supported by KWF Kankerbestrijding and Technology Foundation STW, as part of their joint strategic research programme 'Technology for Oncology' (Grant number 15175).

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

To obtain preliminary data on variability in PSMA expression by comparing prostate uptake

on standard clinical 68Ga-PSMA PET/CT with 68Ga-PSMA PET/CT performed 4 weeks later.

Toelichting onderzoek

Achtergrond van het onderzoek

Prostate cancer is the third most common cancer in Europe and is still the leading cancer among men in the Netherlands with over 13,000 men diagnosed each year. 68-Gallium Prostate Specific Membrane Antigen (68Ga-PSMA) is an emerging imaging agent that already has been widely proven as a highly effective agent for restaging PCa cells, but also holds enormous potential for initial staging and image guided surgery. During surgery, 68Ga-PSMA can potentially be used for the assessment of resection margins based on Cerenkov Light emission. The interval between initial staging and subsequent prostatectomy surgery, however, ranges from 4 to 6 weeks. Since little is known about the PSMA expression over time without intervention, a study on this is required. If PSMA expression is equal between both scans, the inclusion and dose determination for image guided surgery can be based on the clinical 68Ga-PSMA PET/CT scan. In order to validate this, two PET scans will be performed in a test-retest setting in primary prostate cancer patients. Dynamic imaging will be performed in order to get insight when uptake in the prostate is visible. Subsequently this will be used also to establish the ideal timing of surgery after injection. The objective of this study is to obtain preliminary data on variability in PSMA expression by comparing the tracer uptake on conventional clinical 68Ga-PSMA PET/CT with an additional 68Ga-PSMA PET/CT (4 weeks later) within primary prostate cancer patients. Dynamic imaging will be performed in 5 patients in order to get insight when uptake in the prostate is visible.

Doel van het onderzoek

We expect that the second measurement will be different from the first measurement by no more than 10%.

Onderzoeksopzet

Not applicable

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Proven primary prostate carcinoma

- >18 years
- Good knowledge of Dutch language
- Written informed consent
- Underwent a pelvic MRI-scan
- Eligible for 68Ga-PSMA PET/CT
- Lesion bigger than 10mm on MRI, to minimize partial volume effects

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Contraindications for a PET/CT scan.

- Therapy scheduled between scans
- No PSMA expression in the primary tumor on the first PET scan, excluded for the second scan

Onderzoeksopzet

Opzet

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

Controle: N.v.t. / onbekend

Deelname

Nederland
Status: Werving gestart
(Verwachte) startdatum: 01-12-2018
Aantal proefpersonen: 30
Type: Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies
Datum: 03-01-2020
Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 46835
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8263
CCMO	NL64593.031.18
OMON	NL-OMON46835

Resultaten