18F-PSMA-1007 PET/CT in primary staging of prostate cancer

Gepubliceerd: 12-12-2018 Laatst bijgewerkt: 18-08-2022

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

Samenvatting

ID

NL-OMON24419

Bron
Nationaal Trial Register

Verkorte titel
MINT-study

Aandoening

intermediate-high risk prostate cancer, primary staging, diagnostics

Ondersteuning

Primaire sponsor: Canisius Wilhelmina Ziekenhuis
Weg door Jonkerbos 100
6532 SZ Nijmegen
The Netherlands

Overige ondersteuning: Not applicable

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Diagnostic accuracy (sensitivity, specificity, PPV and NPV) of 18F-PSMA-1007 PET/CT for the detection of (regional) lymph node metastases in the initial staging of intermediate-to high risk PCa patients.

Toelichting onderzoek

Achtergrond van het onderzoek

Over the last years, PSMA-targeting imaging strategies are gaining prominence and have been introduced into (inter)national clinical practice for both initial staging and restaging of PCa. Both 68Ga-PSMA and 18F-labelled PSMA ligands appear safe, provide intense tumor uptake and high tumor-to-background ratios, allowing high lesion detectability. However, diagnostic accuracy of the newly developed 18F-PSMA-1007 tracer has not been extensively investigated. Hence, this study aims to determine diagnostic performance of 18F-PSMA-1007 PET/CT in detection of lymph node metastases as compared to histopathological examination following PLND.

Doel van het onderzoek

To improve detection of metastases, radiotracers have been developed for PET/CT imaging: i.e. radiolabelled Prostate Specific Membrane Antigen (PSMA) ligands. Initial studies with Gallium-68 (68Ga-) PSMA showed promising results. The second generation of Fluorine-18 labelled (18F-) PSMA is hypothesized to offer even better diagnostics. Compared to 68Ga-PSMA, 18F-PSMA has a higher image resolution and a longer half-life. The present study therefore aims to determine diagnostic accuracy of 18F-PSMA-1007 PET/CT in initial staging of intermediate- to high risk PCa.

Onderzoeksopzet

Inclusion of patients: 1-1-2019 up to 1-1-2020.

Data analysis: 1-1-2010 up to 1-6-2010

Publication of data: 1-10-2020

Onderzoeksproduct en/of interventie

Not applicable

Contactpersonen

Publiek

Wetenschappelijk

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Biopsy proven adenocarcinoma of the prostate;

2. Indication for (super)extended pelvic lymph node dissection (PLND - with or without robot-assisted laparoscopic prostatectomy);

3. Mentally competent and understanding of benefits and potential burden of the study;

4. Written informed consent;

5. Age ¡Ý18 years.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. History of prior diagnosed or treated PCa.

2. Known concomitant malignancies (except Basal Cell Carcinoma of the skin).

3. Unwillingness or inability to undergo 18F-PSMA-1007 PET/CT.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-01-2019
Aantal proefpersonen:	100
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	12-12-2018
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	NL7428

Register	ID
NTR-old	NTR7670
Ander register	2018-4294 : CMO dossiernummer

Resultaten

Samenvatting resultaten
Not applicable