18F-PSMA-1007 PET to detect primary prostate cancer: a comparative study with mpMRI and correlation to histopathology

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This explorative study aims to investigate the added value of a 18F-PSMA PET to mpMRI in the detection of local prostate cancer lesions.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Miscellaneous and site unspecified neoplasms benign
Study type	Observational invasive

Summary

ID

NL-OMON49534

Source
ToetsingOnline

Brief title
18F-PSMA PET in primary prostate cancer

Condition

- Miscellaneous and site unspecified neoplasms benign

Synonym
Prostate cancer, prostate malignancy

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Radboud Translational

Medicine

Intervention

Keyword: mpMRI, PET, Prostate cancer, PSMA

Outcome measures

Primary outcome

Within each of the three PIRADS groups (1-2, 3, 4-5) the fraction of patients in which the diagnosis based on mpMRI and 18F-PSMA PET might differ. For patients that have conflicting imaging outcomes, the imaging results are compared with the results of the (target) biopsy.

Secondary endpoints will be the radiological state of the disease expressed in the difference in number and size of suspicious lesions, the extent of the disease on 18F-PSMA PET and mpMRI, correlation of the standardized uptake value of the PET to the PSMA expression of the immune-histopathology of the biopsy (e.g. ISUP score). Another explorative endpoint is to perform a cost-effectiveness analysis for the additional use of 18F-PSMA PET based on the final findings.

Secondary outcome

nvt

Study description

Background summary

Rationale: Prostate cancer (PCa) is the second most common diagnosed malignancy in males worldwide, with over 1.2 million new patients diagnosed every year.(1) Since the introduction of prostate-specific antigen (PSA) the primary diagnosis consisted of histologic confirmation by transrectal ultrasound (TRUS)

systematic biopsies.(2) However, in recent years this has changed into performing multi-parametric MR imaging (mpMRI) prior to prostate biopsy.(3) mpMRI has proven to be a valuable tool to avoid unnecessary prostate biopsies and prevents over-treatment of low-grade PCa, while maintaining equal or higher detection rates of high-grade PCa.(4-6) mpMRI comprises of anatomical (i.e. T2-weighted images [T2-WI]) in combination with functional sequences, that is diffusion weighted Images (DWI) representing cellular density, and dynamic contrast-enhanced imaging (DCE-MRI) that depicts vascularity.(7) DWI emerged as the most important functional modality since an inverse relationship between the apparent diffusion coefficient (ADC) value (derived from the DWI), and PCa aggressiveness was established.(8, 9) Prostate MRI is evaluated using the Prostate Imaging-Reporting and Data System (PIRADS).(10) Lesions are given a category score, from 1 (high-grade PCa is unlikely to be present) to 5 (presence of high-grade PCa is highly likely). A PIRADS 3 is an equivocal scan.(10, 11) Nonetheless, mpMRI has room for improvement as its specificity for high-grade tumors is only 37% and local staging is limited with mpMRI.(6, 12) Also, the mpMRI is frequently unclear as 4-39% of detected lesions are classified as PIRADS 3.(13)
Prostate-specific membrane antigen receptor (PSMA) is highly overexpressed by 95% of the prostate cancer cells and seem to positively correlate to aggressiveness of the tumor.(14, 15) PSMA-positron emission tomography (PET) uses this feature by visualizing PSMA expressing prostate tumors.(14, 15) Currently, the PSMA-PET is generally used to detect recurrences or metastases.(16) However, there is an increasing interest for PSMA-PET scans in patients with a primary diagnosis of PCa for staging purposes.(17-19) Yet, there is no published data on the role of PSMA-PET on PCa prior to biopsy in comparison to the detection rate of mpMRI and histopathology.

Study objective

This explorative study aims to investigate the added value of a 18F-PSMA PET to mpMRI in the detection of local prostate cancer lesions.

Study design

This is a prospective single arm explorative study in which 75 patients will receive both mpMRI and PSMA-PET.

Study burden and risks

The study will require time and effort from participating patients. Even though a large portion of these patients will undergo a 18F-PSMA PET scan as part of standard of care, patients with PIRADS 1-2 lesions will undergo a PSMA PET scan which they would normally not get. Moreover, an additional 18F-PSMA PET scan can also be beneficial for patients as the mpMRI can miss PCa.
There is no reported risk for the injection with 18F-PSMA itself as this scan

is already performed for years in thousands of patients and no adverse events have been reported to date. The injection however, contains Fluor-18 which is radioactive (photons). Nevertheless, the radioactive exposure is in the lowest range and comparable with a normal 18F-FDG PET scan, therefore delayed stochastic effects are not expected. Also, a large portion of patients will receive the scan in case of positive biopsy, as part of clinical routine in our hospital. It will not be necessary to repeat the PET scan for these patients.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Suspicion for prostate cancer (e.g. elevated PSA, suspicious rectal examination)

- Males >= 18 years

Exclusion criteria

- Prostate biopsy in the last 6 months
- History of prostate cancer
- Second active malignancy
- Contra-indications for mpMRI or PET: claustrophobia or inability to lay still for the duration of the exam.

Study design

Design

Study phase:	2
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-09-2020
Enrollment:	75
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	18F-PSMA-1007
Generic name:	18F-PSMA-1007

Ethics review

Approved WMO

Date:	14-04-2020
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	22-06-2020
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
EudraCT	EUCTR2020-001387-28-NL
CCMO	NL73559.091.20