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

No registrations found.

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

Summary

ID

NL-OMON24419

Source
NTR

Brief title
MINT-study

Health condition

intermediate-high risk prostate cancer, primary staging, diagnostics

Sponsors and support

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

Source(s) of monetary or material Support: Not applicable

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

a. Diagnostic accuracy (specificity, PPV) of 18F-PSMA-1007 PET/CT for the detection of distant (bone) metastases.

b. Diagnostic accuracy of 18F-PSMA-1007 PET/CT in staging of the primary tumor in the radical prostatectomy specimen.

c. Diagnostic accuracy of 18F-PSMA-1007 PET/CT for different risk groups (according to the d¡¯Amico classification ¨C see chapter 5.1.3), nomogram risk scores, and the size of malignant lymph nodes.

d. Diagnostic performance of 18F-PSMA-1007 PET/CT versus conventional imaging (skeletal scintigraphy, MRI of the prostate) in detection of local tumor site and metastases.

e. Change of management induced by 18F-PSMA-1007 PET/CT findings specifically.

f. Cost-effectiveness of 18F-PSMA-1007 PET/CT versus (super)extended PLND (e.g. mean hospital length of stay, morbidity-associated costs) for the detection of (regional) LNMs.

Study description

Background summary

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.

Study objective

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.

Study design

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

Intervention

Not applicable

Contacts

Public

Scientific

Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2019
Enrollment:	100
Type:	Anticipated

Ethics review

Positive opinion

Date:	12-12-2018
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	NL7428
NTR-old	NTR7670
Other	2018-4294 : CMO dossiernummer

Study results

Summary results
Not applicable