Variability of quantitative Ga68-PSMA PET: a test-retest pilot study

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The objectives of the study are twofold:1) Determination of the absolute values and variability of PSMA uptake in tumour tissue and in normal tissues, including muscles, liver, spleen, bone marrow2) Determination of the absolute values and...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Reproductive neoplasms male malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON43731

Source
ToetsingOnline

Brief title
Ga68-PSMA test-retest study

Condition

- Reproductive neoplasms male malignant and unspecified

Synonym
Prostate cancer with biochemical relapse, recurrent prostate cancer

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis
Source(s) of monetary or material Support: Catharina Ziekenhuis Eindhoven (overhead).,General Electrics Health Care

Intervention

Keyword: Quantitative Ga68-PSMA PET/CT, Recurrent prostate cancer, Signal variability, Test-retest

Outcome measures

Primary outcome

Quantification of absolute PSMA uptake (SUVmax en SUVpeak) and intrapatient

variability of PSMA uptake in tumor lesions and normal tissues, including

muscles, liver, spleen, bone marrow.

Primary endpoints:

Absolute values and intrapatient variability of PSMA uptake in tumor lesions

Absolute values and intrapatient variability of PSMA uptake in muscle

Absolute values and intrapatient variability of PSMA uptake in liver

Absolute values and intrapatient variability of PSMA uptake in spleen

Absolute values and intrapatient variability of PSMA uptake in bone marrow

Absolute values and total variability of PSMA uptake in all tumor lesions

irrespective of size

Secondary outcome

Quantification of absolute values and intrapatient variability in PSMA uptake

in tumour lesions and normal tissue, with or without Q.Clear reconstruction.

Secondary endpoints:

2.2.1 Secundaire eindpunten:

Absolute values and intrapatient variability of PSMA uptake in small tumor lesions < 3 cc, with or without Q.Clear

Absolute values and intrapatient variability of PSMA uptake in non small tumor lesions >= 3 cc, with or without Q.Clear

Absolute values and intrapatient variability of PSMA uptake in muscle, with or without Q.Clear

Absolute values and intrapatient variability of PSMA uptake in liver, with or without Q.Clear

Absolute values and intrapatient variability of PSMA uptake in spleen, with or without Q.Clear

Absolute values and intrapatient variability of PSMA uptake in bone marrow, with or without Q.Clear

Study description

Background summary

The optimal treatment for metastatic prostate cancer depends on characteristics of the tumour and of the patient, and may consist of multiple modalities including hormone, chemo, radiation, and radionuclide therapy. The options for systemic treatment of bone metastases have recently been expanded with the radionuclide Radium-223, providing improved survival with low toxicity. The effectiveness of any treatment should be monitored, in order to refrain from ineffective therapy, unneeded costs and avoidable side effects.

Treatment monitoring in patients with metastatic prostate cancer is difficult, especially with respect to the response of bone metastases. Nor blood testing (PSA), nor radiological imaging (CT or MRI) is sufficiently reliable. Also skeletal scintigraphy is unable to discriminate response and signal flare due to bone repair. Metabolic imaging with FDG-PET has limited sensitivity for prostate cancer and is potentially compromised by inflammation after irradiation. Functional metabolic imaging with other radiolabeled ligands, such as 68Ga-PSMA and positron emission tomography (PSMA-PET) is promising, however.

It is known that uptake measurements of radiolabeled tracers with PET in vivo suffer from many inaccuracies, as demonstrated by experience with FDG, and that this requires evaluation and standardisation prior to application as response parameter. This probably applies equally to PSMA-PET. Before quantification of PSMA uptake can be used as a biological parameter to identify response to treatment, and before we can design sufficiently powered response evaluation studies, we need to know the characteristics of the measurement technique. An important factor that is currently unknown is the normal day-to-day variability in tumour and normal tissues. This signal variability is currently unknown and will be evaluated in this pilot study in a sufficiently large cohort of patients in whom recurrent prostate cancer is suspected.

Q.Clear. With respect to the technical imaging parameters, image reconstruction could be of special interest due to better signal-to-noise ratios (SNRs) that are claimed using a Bayesian penalized reconstruction algorithm called Q.Clear, especially for lesions smaller than 3 cc. It is tempting to speculate that these claimed better SNRs translate into higher absolute values and less total variability of quantitative PSMA uptake in these smaller lesions.

Study objective

The objectives of the study are twofold:
1) Determination of the absolute values and variability of PSMA uptake in tumour tissue and in normal tissues, including muscles, liver, spleen, bone marrow
2) Determination of the absolute values and variability in PSMA uptake in tumour tissue and in normal tissues, with or without Q.Clear.Tumour lesions will be stratified by lesion size.

Study design

Single center prospective observational study, in which the test-retest variation of PSMA uptake in tissues (both tumour and normal) will be determined. Tumour lesions will be divided between small (< 3 cc) and non small (>= 3 cc) lesions. Two data sets will be constructed, one with Q.Clear and one without. The timeframe for the study is two to three years, depending on how many patients are willing to participate. If one out of three is willing to

participate it will be three years. The duration can be reduced to two years if one out of two patients can be included.

Study burden and risks

Patients will not have any benefit from participating in this study, and they will have very limited additional risk. The repeated PSMA PET scan is not expected to provide any clinically relevant new information, it will not be reviewed or reported as such, and it will not have impact on clinical diagnosis or treatment decisions. Patient burden of participation is generated by one additional visit to the hospital of at maximum one hour, one vena punction with one tracer administration, and a total additional radiation burden of ~6 mSv. This radiation burden is in the range of standard diagnostic tools, and is not considered an additional clinically relevant risk in relation to their biochemically recurrent prostate cancer with macroscopic disease.

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

Biochemical recurrence of prostate cancer and
eligible for PSMA PET for restaging and
at least one visually PSMA positive tumour site and
mentally competent

Exclusion criteria

Age < 18 years
Mentally incompetent
Currently on hormone, chemo, radiation or radionuclide treatment

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-01-2018
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	22-03-2017

Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	25-05-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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
CCMO	NL52809.100.16