PILOT Quality check of PSMA PET for imaging salivary gland toxicity

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON42838

Source
ToetsingOnline

Brief title
PILOT Quality PSMA PET for salivary gland toxicity

Condition

- Other condition

Synonym
Salivary gland toxicity, Xerostomia

Health condition

Toxiciteit in speekselklieren van uitwendige bestraling

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: Eigen budget afdeling nucleaire geneeskunde en radiotherapie

Intervention

Keyword: PSMA PET/CT, Quality, Salivary glands, Toxicity

Outcome measures

Primary outcome

The image quality will be evaluated visually with respect to spatial resolution, signal-to-noise levels and artefacts. The signal reduction due to external beam irradiation will be interpreted visually, while considering relatively spared regions and known normal uptake patterns in healthy gland tissues. An expert panel will review if the PSMA PET/CT scans are adequate (feasible) for the application in the anticipated study protocol.

Secondary outcome

Not applicable.

Study description

Background summary

High dose radiotherapy in the head-neck area can result in loss of salivary gland function, with potential serious impact on quality of life. The relation between the received radiation dose and the local function loss in distinct salivary gland subtypes is insufficiently understood, and thus there are currently no known dose constraints or sparing strategies for most gland types. We have already demonstrated that PSMA PET/CT can visualize the presence of acinar cells in all salivary gland locations throughout the head and neck, with a sensitive and quantitative signal. Theoretical considerations suggest that PSMA PET/CT of the salivary glands can be performed with a 50% lower administered tracer dose than the clinical standard, and that a loss of vital

acinar cells after radiotherapy will result in a reduction of PSMA accumulation in salivary glands.
We are now developing a study protocol to determine the relation between the received radiation dose and the development of function loss of salivary glands, separately for distinct salivary gland types and both for the long term and acute phase, using PSMA PET/CT. This information can contribute to the development of dose constraints and sparing strategies, to individualised and adaptive treatment strategies, and hopefully to lower toxicity of radiotherapy and achieve a better quality of life in treated patients.

Study objective

PSMA PET/CT has not been applied before for this indication, or with such a low dose. Before starting the study, we would like to confirm that PSMA PET/CT provides good image quality of the salivary glands with a 50% lower administered tracer dose, and that it provides a measurable signal reduction in case of clinically confirmed function loss of the salivary glands after high dose radiotherapy.

Study design

Patients will receive a single low dose PET/CT (50 MBq Gallium-68-PSMA and low dose CT) of the head and neck area at 6-12 months after their (CC)RT. Image acquisition and processing will be performed according to standard clinical protocols.

Study burden and risks

Participation in this study has no significant risks. Patients will receive one PSMA PET/CT scan of the head-neck area, with a radiation expose of 1 mSv from the administered 50 MBq Gallium-68-PSMA and 3 mSv from low dose CT, for a total of 4 mSv. This is well within the range of normal diagnostic procedures, and does not induce a significant risk in this population with cancer that was treated with high dose radiotherapy. Further patient burden involves one extra visit to the hospital of one hour, and one intravenous injection for administration of the tracer.

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

Patients with HNSCC, who were treated 6-12 months ago with (CC)RT of one neck side with curative intent, and who received variable doses to the major salivary glands at the irradiated side with at least one gland receiving a significant part >36Gy EQD2.

Exclusion criteria

Pregnancy, lactation, inability to provide informed consent

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-08-2016
Enrollment:	5
Type:	Actual

Ethics review

Approved WMO

Date:	12-08-2016
Application type:	First submission
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)

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	NL58445.031.16