68Ga-PSMA-PET/CT imaging for locally advanced, recurrent and metastatic adenoid cystic carcinoma or salivary duct carcinoma

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Primary objective- To evaluate the uptake of 68Ga-PSMA in locally advanced, recurrent and metastatic ACC or SDC by performing 68Ga-PSMA-PET/CT scans.Secondary objectives- To calculate the SUV tumor-to-background ratio and tumor-to-*healthy salivary…

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

Summary

ID

NL-OMON44299

Source
ToetsingOnline

Brief title
PSMA-PET imaging for advanced ACC/SDC

Condition

- Miscellaneous and site unspecified neoplasms benign

Synonym
Adenoid cystic carcinoma, salivary duct carcinoma, salivary gland cancer

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum

Source(s) of monetary or material Support: ACC Research Foundation (patiëntenvereniging VS)

Intervention

Keyword: adenoid cystic carcinoma, Positron-Emission Tomography, PSMA, salivary duct carcinoma

Outcome measures

Primary outcome

Primary objective

- To evaluate the uptake of 68Ga-PSMA in locally advanced, recurrent and

metastatic ACC or SDC by performing 68Ga-PSMA-PET/CT scans.

Secondary outcome

Secondary objectives

- To calculate the SUV tumor-to-background ratio and tumor-to-*healthy salivary

gland tissue* ratio.

- Correlate the tumor uptake (SUV) to the degree of immunohistochemical PSMA

expression of the primary tumor on archival tissue or a fresh biopsy.

- To establish whether new metastatic lesions are found by 68GA-PSMA-PET/CT

imaging.

Study description

Background summary

PSMA is a transmembrane protein and PSMA expression can be visualized and quantified by immunohistochemical staining of tissue biopsies with anti-PSMA monoclonal antibodies. This has been done for many healthy and malignant tissues. PSMA expression appears to be restricted to a few healthy tissues, such as the prostate, duodenum, proximal renal tubules, breast and skeletal muscle.2 Results on PSMA expression of healthy salivary gland tissue are

conflicting. In malignant tissue, PSMA expression was found in prostate cancer cells and the neovasculature of many other solid malignancies, including renal cell carcinoma, bladder cancer, colon cancer, neuroendocrine carcinoma, melanoma, pancreatic cancer, non-small cell lung cancer, breast cancer and others. In ACC, a study in 54 patients showed PSMA expression in 85% of patients, and in 70% of patients with recurrent ACC. In SDC, PSMA expression is currently under study, and the first results show PSMA expression in more than 80% of patients.

Prostate cancer lesions can be targeted efficiently with radiolabeled PSMA ligands. Labeled with 68Ga, PSMA ligands can be used to sensitively detect these tumors noninvasively with PET. Labeled with *-emitting radionuclides such as 177Lu, PSMA ligands are a new class of powerful therapeutics for targeted radionuclide therapy.

In the current study, we will evaluate the uptake of 68Ga-PSMA by performing 68Ga-PSMA-PET/CT scans in locally advanced, recurrent and metastatic ACC or SDC patients. If the uptake is high, this forms the rationale for a therapeutic study with 177Lu-PSMA.

Study objective

Primary objective
- To evaluate the uptake of 68Ga-PSMA in locally advanced, recurrent and metastatic ACC or SDC by performing 68Ga-PSMA-PET/CT scans.

Secondary objectives
- To calculate the SUV tumor-to-background ratio and tumor-to-*healthy salivary gland tissue* ratio.
- Correlate the tumor uptake (SUV) to the degree of immunohistochemical PSMA expression of the primary tumor on archival tissue or a fresh biopsy.
- To establish whether new metastatic lesions are found by 68GA-PSMA-PET/CT imaging.

Study design

Diagnostic study

Intervention

Study procedure
1. Before screening visit:
- Eligible patients will be informed about the study during normal patient care. If the patient is considering to participate, a screening visit will be planned.
2. Screening visit:

- Review of inclusion and exclusion criteria.
- Obtain written informed consent.
- Review of demographic data, medical history, allergies, and vital signs.
- Asses serum AST, ALT, and creatinine unless done within 14 days prior to visit.
3. Study visit:
- Perform a 68Ga-PSMA-PET/CT scan according to standard protocol. 68Ga-PSMA will be administered in a single intravenous dose of 2 MBq/kg in order to obtain images with PET/CT.
4. Additional analysis: determination of the immunohistochemical PSMA expression on the most recent tissue material. The patient gives consent for this analysis, but doe'sn't have to undergo additional procedures.

Study burden and risks

A patient who decides to participate in this study will need to make 2 extra visits to the Radboudumc. During the first visit an informed consent will be signed and the background variables will be taken. During the second visit the 68Ga-PSMA-PET/CT scan will be made. These two visits will take approximately 3 hours in total. The participant is not expected to have complaints from these procedures and the risks are minimal. The participant will not benefit from participating in the study. If this study is successful we will pursue a therapeutic study with 177Lu-PSMA from which the participant may benefit.

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

- locally advanced, recurrent or metastatic ACC or SDC
- Age * 18 years old
- Ability to provide written informed consent

Exclusion criteria

- Contra-indication for PET imaging: pregnancy, breast feeding, severe claustrophobia
- Impaired renal function: MDRD <30 ml/min/1,73 m2
- Impaired liver function: AST and ALT * 2.5 x ULN (*5 x ULN for patients with liver metastases)

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):	13-11-2017
Enrollment:	25

Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	68Gallium-PSMA
Generic name:	68Gallium-PSMA

Ethics review

Approved WMO Date:	08-06-2017
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	30-08-2017
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	EUCTR2017-002093-40-NL
CCMO	NL61699.091.17