Effect of androgen deprivation therapy on uptake of PSMA ligand in patients with salivary duct carcinoma: an explorative study.

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

Summary

ID

NL-OMON48488

Source
ToetsingOnline

Brief title
ADT-SCAN

Condition

- Miscellaneous and site unspecified neoplasms benign

Synonym
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: KWF beurs

Intervention

Keyword: androgen deprivation therapy, positron emission tomography, prostate specific membrane antigen, salivary duct carinoma

Outcome measures

Primary outcome

The percentage of patients with an ADT induced increase in PSMA ligand uptake

on 68Ga-PSMA-PET/CT.

Secondary outcome

- standardised uptake values (SUV) of recurrence and/or metastases in

68Ga-PSMA-PET/CT pre- and post ADT.

- standardised uptake values of recurrence and/or metastases in 18FDG-PET/CT

pre- and post ADT.

- correlation between SUV and the degree of immunohistochemical PSMA

expression.

Study description

Background summary

Prostate specific membrane antigen (PSMA) is a transmembrane protein, which is expressed on prostate cancers cells and other malignancies. Recently, several ligands have been developed that target PSMA. Linked to Gallium-68, this enables diagnostic
68Ga-PSMA-PET/CT scans. Linked to Lutetium-177 enables therapeutic 177Lu-PSMA Radioligand therapy. Most research on the diagnostic and therapeutic possibilities of PSMA has been conducted in patients with advanced prostate cancer.
Our research group investigates whether these findings also apply to salivary gland cancer (SGC), a rare cancer. Previously we conducted a phase II 68Ga-PSMA imaging study, to evaluate PSMA ligand uptake in locally advanced, recurrent and metastatic ACC and SDC (two subtypes of SGC). We observed intense PSMA-ligand uptake in 93% of ACC patients and 40% of SDC patients. A phase II

therapeutic study with 177Lu-PSMA RLT in advanced SGC will follow (upcoming study).
However, since 60% of SDC patients showed low ligand uptake, they are not suitable for this therapy. For advanced SDC, androgen deprivation therapy is often given as first-line treatment, because the majority of SDCs are androgen receptor positive.
In prostate cancer, androgen deprivation therapy (ADT) can increase PSMA-ligand uptake. Therefore we aim to investigate if ADT can increase the uptake of 68Ga-PSMA in patients with R/M SDC, as has previously been demonstrated in prostate cancer.

Study objective

The primary objective is to investigate if ADT can increase the uptake of 68Ga-PSMA in patients with R/M SDC.

Study design

Interventional clinical trial, an explorative study.

Study burden and risks

Participants will undergo two 68Ga-PSMA-PET/CT, two 18FDG-PET/CT and venapunctures. These are standard diagnostic procedures with a known minimal safety risk. The participant will be asked to make five study related visits. A participant will not benefit from participating in this study. The study does not involve minor or incapacitated subjects.
Optional part: one or two biopsies.

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 must have the ability to provide written informed consent.
• Patients must be >= 18 years of age.
• Patients must have histological, pathological, and/or cytological confirmation of salivary duct carcinoma, androgen receptor positive.
• Only patients with locally advanced, recurrent or metastatic salivary duct carcinoma can participate.
• Patients must have at least one lesion with a diameter of >= 1.5 cm.
• Patients whom intend to start androgen deprivation therapy, after this has been re-commended by the treating physician as standard treatment.

Exclusion criteria

• Contra-indication for PET imaging: pregnancy or breast feeding or severe claustrophobia
• Impaired renal function: MDRD <30 ml/min/1,73 m2
• Impaired liver function: AST and ALT 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:	Completed
Start date (anticipated):	05-11-2020
Enrollment:	14
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO Date:	27-08-2019
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	07-11-2019
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	EUCTR2019-003262-41-NL
CCMO	NL71139.091.19

Study results

Date completed: 10-07-2024

Actual enrolment: 9

Summary results
Trial ended prematurely