177Lu-PSMA Radioligand Therapy for advanced salivary gland cancer, a phase II pilot study.

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To evaluate the safety and efficacy of 177Lu-PSMA RLT in patients with R/M ACC and SDC with PSMA ligand uptake.

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

Summary

ID

NL-OMON48525

Source
ToetsingOnline

Brief title
LUPSA

Condition

- Miscellaneous and site unspecified neoplasms benign

Synonym
salivary gland cancer

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: KWF

Intervention

Keyword: PSMA, radioligand therapy, salivary gland cancer

Outcome measures

Primary outcome

Safety

Secondary outcome

- Efficacy: by objective response rate (ORR)

- Progression free survival (PFS)

- Overal survival (OS)

- Duration of response (DoR)

- Quality of life (QoL)

- delivered dose

- radiation toxicity

- to explore differences in tumor mutational burden, immunohistochemical

expression profiles and intracellular pathways between responding and

non-responding patients

Study description

Background summary

Salivary gland cancer (SGC) is one of the rare cancers. Treatment options for incurative local or regional recurrences and/or metastatic (R/M) SGC are limited and therefore new treatment options are urgently needed. Radioligand therapy (RLT) is a promising new therapeutic approach to treat advanced prostate cancer. Lutetium-177 (177Lu, β-emitter) labelled PSMA is a highly effective treatment directed against prostate-specific membrane antigen (PSMA), which is overexpressed in prostate cancer cells. A previous imaging study showed there is also PSMA expression in two frequently occurring subtypes

of SGC: adenoid cystic carcinoma (ACC) and salivary duct carcinoma (SDC). Therefore we consider 177Lu-PSMA RLT a potential new treatment option for these subtypes of SGC.

Study objective

To evaluate the safety and efficacy of 177Lu-PSMA RLT in patients with R/M ACC and SDC with PSMA ligand uptake.

Study design

Phase II pilot study, single centre, two cohorts.
Cohort 1: Patients with R/M ACC, 4 cyles of 7.4 GBq 177Lu-PSMA every 6 weeks.
Cohort 2: Patients with R/M SDC, 4 cyles of 7.4 GBq 177Lu-PSMA every 6 weeks.

Intervention

Repeated intravenous application of 7.4 GBq (gigabequerel)(±10%) 177Lu-PSMA every 6±1 weeks; until reaching four cycles.

Study burden and risks

Burden and risks: During the 3 years of the study, patients will make approximately 30 study related visits. 5 PET-CT, 5 SPECT-CT and 10 CT scans will be made. During outpatient visits blood samples will be taken for safety assessments together with additional blood samples for research purposes (e.g. pharmacokinetic studies, response assessment). Patients will be asked to fill in questionnaires 6 times.
A potential risk is the therapeutic injection with 177Lu-PSMA itself, as it is not yet completely clear what the short and long-term toxicity profile of this new therapeutic approach is. However in patients with prostate cancer this therapy is relatively well-tolerable with low side-effect profile.

Benefit: Treatment with 177Lu-PSMA could lead to response or stabilize previously progressive disease and therefore potentially prolong survival. It may improve the quality of life of patients whom experience any kind of discomfort due to the progression of their 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

- Patients must have the ability to provide written informed consent.
- Patients must be >= 18 years of age.
- Patients must have an ECOG performance status of 0 to 2.
- Patients must have histological, pathological, and/or cytological confirmation of either adenoid cystic carcinoma or salivary duct carcinoma.
- Patients must have incurable, local or regional recurrent or metastatic ACC or SDC.
- Patients with ACC can only participate in case of objective growth in the last three months or complaints due to the disease.
- Patients must have adequate organ function:
Sufficient bone marrow capacity as defined by: WBC count (white blood cell) >=2.5x10^9/L, PLT (platelet) count >=100x10^9/L, Hb >=6 mmol/L, absolute neutrophil count (ANC) >=1.5x10^9/L
Adequate liver function as defined by: Total bilirubin <=1.5 x ULN. For patients known with Gilbert*s Syndrome <= 3 x ULN is permitted. Alanine aminotransferase (ALT) and aspartate aminotransferase (AST) <=3.0 × ULN OR <=5.0 × ULN for patients with liver metastases.
Adequate kidney function as defined by: Serum creatinine <=1.5 x ULN or creatinine clearance >= 50 mL/min

- Patients must have measurable disease at baseline. Defined as >= 1 lesion >= 2 cm (long axis) that is present on baseline CT.
- Patients must have a positive 68Ga-PSMA PET/CT scan, defined by at least one lesion >= 1.5 cm (long axis) with a ligand uptake above liver level.

Exclusion criteria

- Patients whom are pregnant or breast feeding.
- Patients with reproductive potential not implementing adequate contraceptives measures.
- Patients with known brain metastases or cranial epidural disease or intracardial metastases.
- Patients with concurrent serious (as determined by the Principal Investigator) medical conditions, including, but not limited to, New York Heart Association class III or IV congestive heart failure, history of congenital prolonged QT syndrome, uncontrolled infection, active hepatitis B or C, or other significant comorbid conditions that in the opinion of the investigator would impair study participation or cooperation.
- Patients with urinary tract obstruction or marked hydronephrosis
- Less than 4 weeks since last myelosuppressive therapy or other radionuclide therapy.
- Concomitant cancer treatments

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	16-07-2020
Enrollment:	10

Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Lutetium-177-PSMA-I&T
Generic name:	Lutetium-177-PSMA-I&T

Ethics review

Approved WMO Date:	09-12-2019
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	23-01-2020
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	12-03-2020
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	16-02-2021
Application type:	Amendment
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	EUCTR2019-003857-27-NL
CCMO	NL71624.091.19

Study results

Date completed:	01-10-2023
Results posted:	02-09-2024
Actual enrolment:	12

First publication
02-09-2024