Pilot study to evaluate dosimetry and toxicity of lutetium-177-PSMA-617 radioligand therapy in low volume, hormone sensitive metastatic prostate cancer

Published: 29-11-2017
Last updated: 12-04-2024

The aim of this study is to evaluate the dosimetry and toxicity of Lutetium-177-PSMA-617, in patients with low volume, hormone sensitive metastatic prostate cancer.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Renal and urinary tract neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON46596

Source
ToetsingOnline

Brief title
Pilot study: Lutetium-177-PSMA-617 in low volume metastatic prostate cancer

Condition

- Renal and urinary tract neoplasms malignant and unspecified
- Prostatic disorders (excl infections and inflammations)

Synonym
prostate cancer, Prostate carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Prostate cancer, PSMA, PSMA-617 radioligand therapy, Therapy

Outcome measures

Primary outcome

- To calculate the doses delivered by Lutetium-177-PSMA-617 radioligand therapy in patients with low volume, hormone sensitive metastatic prostate cancer

- To determine the toxicity (focusing on radiation doses to organs at risk) of Lutetium-177-PSMA-617 radioligand therapy in patients with low volume, hormone sensitive metastatic prostate cancer

Secondary outcome

- To evaluate the clinical efficacy of multiple doses Lutetium-177-PSMA-617 radioligand therapy in patients with low volume, hormone sensitive metastatic prostate cancer by:

1. the changes in PSA values after Lutetium-177-PSMA-617 RLT

2. the changes on uptake of Gallium-68-PSMA-617 PET/CT before and 6 months after Lutetium-177-PSMA-617 RLT

3.To evaluate the changes in number and size of metastatic lymph nodes on nano-MRI before and 3 months after Lutetium-177-PSMA-617 RLT)

- To evaluate the quality of life after Lutetium-177-PSMA-617 RLT

Study description

Background summary

Lutetium-177-PSMA-617 has been evaluated in end stage prostate cancer patients extensively. Although the results of these studies are promising, all currently available data are retrospective.

Interestingly, radioligand therapy is known to be more effective in low volume disease in several tumor types, because of the very high tumor uptake of radioligands in small lesions. This is the ratio for current prospective study: radioligand therapy with Lutetium-177-PSMA-617 is possibly more effective in low-volume disease. In this study, we will evaluate the dosimetry in small volume disease. In future studies, efficacy will be assesed more extensively.

Study objective

The aim of this study is to evaluate the dosimetry and toxicity of Lutetium-177-PSMA-617, in patients with low volume, hormone sensitive metastatic prostate cancer.

Study design

Observational

Intervention

Infusion of Lutetium-177-PSMA-617

Study burden and risks

It is expected that treatment with Lutetium-177-PSMA-617 (first dose of 3 GBq and second dose according to dosimetry results) will lead to transient myelotoxicity and xerostomia.
In previous studies with high activity doses (~5.6 GBq), transient grade 3-4 myelotoxicity was observed in 12% of the participants. Transient xerostomia was seen in 8% of the patients. In theory, nephrotoxicity is possible due to the fact that the radioligand is cleared via the kidneys. However,no grade 3-4 nephrotoxicity was observed in previous studies. Because of de low activity doses used in our study, the risk of nephrotoxicity is considered to be very low.

In total, the hospital visits will take approximately 65 hours.

Contacts

Public
Radboud Universitair Medisch Centrum

Geert Grooteplein 10
Nijmegen 6525 GA
NL
Scientific
Radboud Universitair Medisch Centrum

Geert Grooteplein 10
Nijmegen 6525 GA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Histological proven adenocarcinoma of the prostate ;- Prior local therapy for prostate cancer;- Biochemical recurrence or clinical progression after local therapy (PSA > 0.2 µg/l), PSA-DT < 6 months);- 68Ga-PSMA-PET-CT positive metastases in bones and/or lymph nodes (N1/M1ab): *1, maximally 10 metastases (minimal lesion size 1 cm to enable adequate dosimetry studies) ;- Local treatment for oligometastases with radiotherapy or surgery appears to be no option anymore (due to prior treatment or the location of the metastatic lesions);- No prior hormonal therapy or chemotherapy; testosteron > 1.7 nmol/l. ;Exception: local prostate cancer treated with local radiotherapy plus adjuvant ADT; these patients need to be stopped with ADT at least 3 months;- No visceral metastases ;- Laboratory values: ;* White blood cells * 3.5 x 10^9/l ;* Platelet count * 150 x 10^9/l ;* Hemoglobin * 6 mmol/l ;* ASAT, ALAT * 3 x ULN ;* MDRD-GFR * 60 ml/min ;-Signed informed consent

Exclusion criteria

- A known subtype other than prostate adenocarcinoma;- Any medical condition present that in the opinion of the investigator will affect patients* clinical status when participating in this trial. ;- Prior hip replacement surgery potentially influencing performance of PSMA PET/CT and nanoMRI;- Contra-indication for MRI imaging (claustrophobia, implanted electric and electronic devices (heart pacemakers, insulin pumps, implanted hearing aids, neurostimulators), intracranial metal clips, metallic bodies in the eye)

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-09-2018
Enrollment:	10
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Lutetium-177-PSMA-617
Generic name:	NA

Ethics review

Approved WMO

Date:	29-11-2017
Application type:	First submission

Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	23-01-2018
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	02-07-2018
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	EUCTR2017-003122-32-NL
CCMO	NL62774.091.17