First line Lutetium-177-PSMA-617 radioligand therapy in metastatic castrate resistant prostate cancer.

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Ethical review	Not approved
Status	Will not start
Health condition type	Metastases
Study type	Interventional

Summary

ID

NL-OMON45803

Source
ToetsingOnline

Brief title
First line Lu-177-PSMA-617 radioligand therapy in mCRPC.

Condition

- Metastases
- Prostatic disorders (excl infections and inflammations)

Synonym
adenocarcinoma of the prostate; prostate cancer

Research involving
Human

Sponsors and support

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

oncologiefonds;prostaatkankerstichting

Intervention

Keyword: mCRPC, PSMA, radioligand, therapy

Outcome measures

Primary outcome

The primary endpoint is the therapy response defined as decline of PSA value of

> 50%.

Secondary outcome

Not applicable.

Study description

Background summary

A novel radiation-based treatment for PCa is radionuclide therapy targeting Prostate-Specific Membrane Antigen (PSMA), a protein which is overexpressed in PCa cells.[2] PSMA ligands can be labeled with radioisotopes such as the beta-emitter Lutetium-177 (Lu-177). Treatment of patients with this compound results in high radiation doses specifically on PSMA expressing tumors. This therapy is called PSMA-specific radionuclide therapy (Lu-177-PSMA) and offers several advantages above Radium-223 as it targets all tumor lesions in the body, not only bone metastases. Moreover, PSMA-targeted radionuclide therapy is PSMA-specific, which selectively limits radiation damage to PSMA-expressing tissues and reduces damage to healthy tissues. Lu-177-PSMA therefore combines high tumoricidal effects with low toxicity.

Study objective

The primary aim of this first line 177Lu-PSMA RLT study is to evaluate the clinical efficacy in castration resistant metastatic prostate cancer. Secondary aims are to assess the progression free survival (radiographic, clinical or PSA progression free survival), the response to 177Lu-177 PSMA RLT (RECIST 1.1, metabolic, biomarkers), the safety and tolerability, the health-related quality of life assessment and pain assessment, and the overall survival.

Study design

This is a multicentric, single arm and open label phase II study.

Intervention

Treatment of mCRPC with a maximum of 6 cycles of 177Lu-PSMA-617 radioligand therapy.

Study burden and risks

As standard of care, patients will undergo a 68Ga/18F-PSMA PET/CT scan prior to inclusion. For this study, PSMA-PET/CT imaging will be performed after every two cycles and about 6 and 12 months after completion of therapy.
A potential risk is the therapeutic injection with 177Lu-PSMA-617 itself, as it is not yet completely clear what the short and longterm toxicity profile of this new therapeutic approach is. However, it is important to note that treatment with 177Lu-PSMA-617 shows potential in stabilization of previously progressive 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

1. Male aged 18 or older with metastatic adenocarcinoma of the prostate;
2. Metastatic castrate-resistant prostate cancer without any previous treatments;
3. Progressive disease with rising PSA on 3 consecutive measurements, and PSA * 20 ng/mL;
4. Target or non-target lesions > 1.5 cm in diameter according to RECIST 1.1;
5. Significant PSMA avidity on 68Ga/18F-PSMA PET/CT
6. ECOG Performance status 0 to 2;
7. Adequate renal function;
8. Adequate bone marrow function;
9. Adequate liver function;
10. Willing and able to comply with all study requirements;
11. Signed, written informed consent.

Exclusion criteria

1. Known brain metastasis;
2. Site(s) of disease that show minimal PSMA expression;
3. Sjogren's syndrome;
4. Prior treatment with 177Lu-PSMA-617;
5. Prior chemotherapy or androgen receptor inhibition therapy;
6. Contraindications to the use of corticosteroid treatment;
7. Active malignancy other than prostate cancer, except for patients with basal or squamous skin cancer, and carcinoma in situ of the bladder;
8. Imminent spinal cord compression;
9. Concurrent illness, including severe infection that may jeopardise the ability of the participant to undergo the procedures outlined in this protocol with reasonable safety;
10. Presence of any psychological, familial, sociological or geographical condition potentially hampering compliance with the study protocol and follow-up schedule, including alcohol dependence or drug abuse;
11. Any condition which, in the opinion of the investigator, would preclude participation in this trial;
12. Patients who are sexually active and not willing/able to use medically acceptable forms of barrier contraception.

Study design

Design

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	50
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	[177Lu]Lu-PSMA-617
Generic name:	[177Lu]Lu-PSMA-617

Ethics review

Approved WMO

Date:	03-10-2018
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Not approved

Date:	19-02-2019
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	EUCTR2018-003088-79-NL
CCMO	NL66722.091.18