Registry of Treatment Outcomes in a non-study population of Symptomatic Metastasized Castration Resistant Prostate Cancer (mCRPC) Patients Treated with Radium-223 (ROTOR-registry).

Published: 14-10-2015
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1.To evaluate the efficacy of Radium-223 treatment in a non-study population by effects on Symptomatic Skeletal Event (SSE)2. Evaluate Radium-223 treatment efficacy by patient reported analgesic use and pain outcome3. Evaluate Radium-223 treatment...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Reproductive and genitourinary neoplasms gender unspecified NEC
Study type	Observational non invasive

Summary

ID

NL-OMON55579

Source
ToetsingOnline

Brief title
Radium-223 in mCRPC patients registry/ROTOR-registry

Condition

- Reproductive and genitourinary neoplasms gender unspecified NEC

Synonym
bone metastases, Prostate cancer

Research involving

Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: Farmaceutisch bedrijf Bayer

Intervention

Keyword: mCRPC patients, Radium-223, Registry

Outcome measures

Primary outcome

To evaluate the efficacy of Radium-223 treatment in a non-study population by

effects on Symptomatic Skeletal Event (SSE)

Secondary outcome

To Evaluate Radium-223 treatment efficacy by patient reported analgesic use and

pain outcome.

Study description

Background summary

Every year approximately 12,000 men are diagnosed with prostate cancer in the Netherlands and approximately 2,400 die of this disease. When prostate cancer is limited to the prostate, patients can be operated or radiated with a curative intention, however, metastasized disease is incurable. Initially, prostate cancer responds to testosterone at castration level and treatment with androgen receptor signaling inhibitors. However, after an average of 24 months, prostate cancer will reach a castration resistant stage (mCRPC), which is associated with high morbidity and mortality. Since the introduction of Docetaxel in 2004, multiple treatments for mCRPC have become available. All these treatments have a proven beneficial effect on quality of life and all expand life expectancy. An important clinical problem is that approximately 50% of older patients are not able or not willing to receive docetaxel treatment. These patients are also not eligible for treatments of docetaxel refractory disease. Therefore, there is a need for effective treatments with little site effects.

In the phase 3, ALSYMPCA study 921 patients were randomized between Rad-223 (Xofigo®) and placebo in a 2:1 distribution1. Patients with symptomatic bone metastases, limited lymph node involvement, adequate bone marrow, kidney and liver functions were included in this trial. Patients were previously treated with docetaxel or could not receive docetaxel, declined docetaxel or docetaxel was not available. At a planned interim analysis after 538 deaths, the primary end point overall survival (OS) was 14.9 months in the Radium-223 treated arm and 11.3 months in the placebo arm (HR 0.70; 95% CI 0.58-0.83). All secondary end points were at the favor of Radium-223 treated patients, including time to first skeletal related event, quality of life and various biochemical end points. However, patient reported pain scores were not collected in the trial. Radium-223 treatment was well tolerated, with the most prominent side effects (all grades) thrombocytopenia 12 and 6%, neutropenia 5 and 1% and diarrhea 25 and 15% in the Radium-223 and placebo arm, respectively.
A post-hoc analysis showed an equal efficacy of Radium-223 treatment in docetaxel pre-treated patients as in docetaxel naïve patients.
In this registry we aim to evaluate the efficacy of Radium-223 treatment and first subsequent therapy in a non-study population. Various parameters will be collected, including changes in patient reported pain score. Moreover, changes in serum and blood levels of biomarkers of bone metabolism and levels of blood osteoclast precursors in Radium-223 treated patients will be evaluated for their potential to predict treatment outcome. Frequencies of osteoclastprecursors (GMODP/MODP) of radium-223 patients, will be compared to the frequencies of osteoclastprecursors in patients with localized prostate cancer, without bone metastases.

Study objective

1.To evaluate the efficacy of Radium-223 treatment in a non-study population by effects on Symptomatic Skeletal Event (SSE)
2. Evaluate Radium-223 treatment efficacy by patient reported analgesic use and pain outcome
3. Evaluate Radium-223 treatment efficacy in a non-study population of CRPC patients by clinical parameters.
4. Evaluate Radium-223 treatment tolerability in a non-study population of CRPC patients.
5. Evaluate the efficacy of the first subsequent therapy by clinical parameters
6. Identification of predictive clinical and explorative biomarkers of Radium-223 efficacy
7. Substudy: Test if the frequency of GMODP/MODP (osteoclast precursors) could be used as a predictive biomarker for response on radium-223 treatment in mCRPC patients with bone metastases

Study design

This registry aims to evaluate the efficacy of Rad-223 treatment in a non-study

population of CRPC patients treated earlier with Docetaxel and patients not treated earlier with Docetaxel and efficacy of the first subsequent therapy. The indication for treatment with Radium-223 will be at the physician*s decision. All patients treated with Radium-223 can be included in this registry. The registry only dictates the collection of base line characteristics, expansion of regular blood tests and patient reported pain scores.

Study burden and risks

The only burden associated with this registry are the monthly questionnaires and the extra blood withdrawals.

Substudy (osteoclastprecursors): For the control group in the substudy, the blood withdrawals are the extra burdon. (They will not fill out qny questionnaires.)

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

- At the physicians discretion
- Written informed consent
- Age 18 year of older

Exclusion criteria

- At the physicians discretion

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-12-2015
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	14-10-2015
Application type:	First submission

Review commission:	METC NedMec
Approved WMO Date:	29-01-2016
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	10-03-2016
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	26-04-2018
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	29-11-2018
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	11-01-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	16-01-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	30-04-2021
Application type:	Amendment
Review commission:	METC NedMec

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
CCMO	NL53062.031.15