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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON19873

Source
Nationaal Trial Register

Brief title
ROTOR - registry

Health condition

Radium-223; prostate cancer

Sponsors and support

Primary sponsor: Netherlands Cancer Institute-Antoni van Leeuwenhoek hospital
Source(s) of monetary or material Support: Bayer B.V.

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

1. Evaluate Radium-223 treatment efficacy in a non-study population of CRPC patients by clinical parameters.

2. Evaluate Radium-223 treatment tolerability in a non-study population of CRPC patients.

3. Evaluate the efficacy of the first subsequent therapy by clinical parameters

6. Identification of predictive clinical and explorative biomarkers of Radium-223 efficacy

Study description

Study objective

Radium-223 is the 5th treatment for metastasized castration resistant prostate cancer with a proven overall survival benefit. The improved survival of Radium-223 over placebo was demonstrated in the ALSYMPCA trial, which included a miscellaneous patient population both docetaxel pretreated and non-pretreated. This registry aims to describe non-study patients treated with Radium-223 and prospectively evaluate treatment outcomes of patients with and without docetaxel pretreatment. Analgesic use and patient reported pain scores, efficacy of the subsequent therapy and overall survival will be evaluated. Moreover, clinical and explorative serum and blood biomarkers of Radium-223 efficacy will be explored.

Study design

Every participating hospital will be visited for data entry at least annually.

Intervention

This registry aims to evaluate the efficacy of Radium-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 registry only dictates the collection of base line characteristics, expansion of regular blood tests and patient reported pain scores.

Contacts

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Eligibility criteria

Inclusion criteria

1. At the physicians discretion

Exclusion criteria

1. At the physicians discretion

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-04-2015
Enrollment:	300
Type:	Anticipated

Ethics review

Positive opinion

Date:	16-03-2015
Application type:	First submission

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
NTR-new	NL4734
NTR-old	NTR5075
Other	PTC14.103 : ROTOR

Study results