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

Gepubliceerd: 16-03-2015 Laatst bijgewerkt: 13-12-2022

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Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON19873

Bron
Nationaal Trial Register

Verkorte titel
ROTOR - registry

Aandoening

Radium-223; prostate cancer

Ondersteuning

Primaire sponsor: Netherlands Cancer Institute-Antoni van Leeuwenhoek hospital
Overige ondersteuning: Bayer B.V.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. At the physicians discretion

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. At the physicians discretion

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders

Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-04-2015
Aantal proefpersonen:	300
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	16-03-2015
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4734
NTR-old	NTR5075
Ander register	PTC14.103 : ROTOR

Resultaten