

Docetaxel Impact on Metastatic Prostate cancer patients: a quality of Life Evaluation

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QoL diminishes more during the same chemotherapy if it is administered at a later moment time point

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON29025

Bron

NTR

Verkorte titel

Dimple

Aandoening

Prostate cancer

Ondersteuning

Primaire sponsor: none

Overige ondersteuning: internal grant

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Primary endpoint

Does the change of QoL differ during the time of treatment with docetaxel with respectively HSPC versus 1st line and 2nd line CRPC?

Toelichting onderzoek

Achtergrond van het onderzoek

Each year, over 1 million men are diagnosed with prostate cancer world-wide, rendering it the most common diagnosed non-cutaneous cancer in males. Approximately 250.000 patients succumb each year to the consequences of the disease, making prostate cancer the second-largest cause of cancer-related deaths in men. In 2019, 13.600 men have been diagnosed with prostate cancer in the Netherlands. Although localized prostate cancer can be treated with a curative intent, the metastatic disease cannot. According to the literature, the number of prostate cancer patients is increasing every year, and its treatment is having a major impact on quality of life. For caregivers and physicians, it is very important to know more about the patient's quality of life (QoL) during the treatment with docetaxel so that professional help can be called in if necessary. Moreover, the influence on QoL of the treatment with docetaxel is also an important aspect when a decision has to be made with the patient and the physicians for the future therapy.

The systemic treatment for patients with metastatic prostate cancer contains androgen deprivation therapy, androgen-signalling targeting agents, chemotherapy (docetaxel, cabazitaxel), PARP-inhibition and radium-223.

Docetaxel can be administered as a part of the initial therapy for men with metastatic disease (metastatic hormone sensitive prostate cancer; mHSPC) or as one of the lines of therapy for metastatic castration refractory prostate cancer (mCRPC).

Quality of life is a combination of physical, mental and spiritual aspects in life, whether or not caused by the disease. These aspects are preferred because the work is performed from a holistic view of human beings. Mental and physical well-being influence each other and, it is important to pay attention to both aspects. Attention to QoL in patients is therefore essential for the treating physicians.

Prostaatonline is a web based tool, developed to support patients during the course of the disease and treatment. Prostaatonline is one of the modules on Curavista.health and as such CE marked and compliant with EU regulations on data protection. Curavista.health is the engine that offers a modular Personal Health Record for patients connected to the Electronic Health Records. The engine is CE class I MDR certified, Curavista® as well as the datacenter Bytenet are NEN 7510 and ISO27001 certified.

The influence on the quality of life differs with the stage of development of the disease and with the treatment. Numerous studies have shown that docetaxel can diminish QoL; however, currently no robust data are available if the impact regarding the QoL differs between the several lines that docetaxel can be administered in patients with metastatic prostate cancer (mPC).

Given the fact that one of the goals of treating men with mPC is preserving QoL the impact does influence therapeutic choices.

Doel van het onderzoek

QoL diminishes more during the same chemotherapy if it is administered at a later moment time point

Onderzoeksopzet

at inclusion and every 3 months during participation in prostaatonline

Onderzoeksproduct en/of interventie

NA

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Age $\geq$ 18 year
- Prostaatonline-participant (Patients that gave approval (in prostaatonline) for the use of data for scientific purposes)
- Treatment with docetaxel during the time of participation in prostaatonline

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

None

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	07-02-2021
Aantal proefpersonen:	300
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Niet van toepassing	
Soort:	Niet van toepassing

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
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NTR-new	NL9285
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Ander register non-WMO approval by Franciscus Gasthuis & Vlietland Academy : 2020-123

Resultaten

Samenvatting resultaten

NA