

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

No registrations found.

<b>Ethical review</b>	Not applicable
<b>Status</b>	Pending
<b>Health condition type</b>	-
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON29025

### Source

NTR

### Brief title

Dimple

### Health condition

Prostate cancer

## Sponsors and support

**Primary sponsor:** none

**Source(s) of monetary or material Support:** internal grant

## Intervention

## Outcome measures

### Primary outcome

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?

## Secondary outcome

Secondary endpoint

- What is the change in QoL at the time of treatment with docetaxel in patients with metastatic prostate cancer?
- What is the absolute QoL after the last cycle from one series of treatment with docetaxel?
- What is the QoL six months after the last docetaxel in one series?

## Study description

### Background summary

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.

### **Study objective**

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

### **Study design**

at inclusion and every 3 months during participation in prostaatonline

### **Intervention**

NA

## **Contacts**

### **Public**

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### **Scientific**

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## **Eligibility criteria**

### **Inclusion criteria**

- 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

## Exclusion criteria

None

## Study design

### Design

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

### Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	07-02-2021
Enrollment:	300
Type:	Anticipated

### IPD sharing statement

**Plan to share IPD:** No

## Ethics review

Not applicable	
Application type:	Not applicable

## 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 NL9285

Other non-WMO approval by Franciscus Gasthuis & Vlietland Academy : 2020-123

## Study results

### Summary results

NA