

# Liquid biopsy in prostate cancer

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- special attention for the development and harmonization of the pre-analysis of liquid biopsy, for blood as well as urine, and next to this for ctDNA as well as ctRNA- special attention for the detection of AR-V7 in blood and urine- special...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Renal and urinary tract neoplasms malignant and unspecified
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON49655

### Source

ToetsingOnline

### Brief title

LiBiPros

### Condition

- Renal and urinary tract neoplasms malignant and unspecified

### Synonym

metastasized castrate-resistant prostate cancer, prostate carcinoma

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Zuyderland Medisch Centrum

**Source(s) of monetary or material Support:** Pfizer, Research & Innovatiefonds Zuyderland

### Intervention

**Keyword:** blood, circulating DNA, prostate carcinoma, tumor heterogeneity

## Outcome measures

### Primary outcome

- relation between the absence/presence of specific mutations in blood vs primary tumor (with special attention to AR-V7 and BRCA 1/2)
- response on therapy

### Secondary outcome

- relation between the absence/presence of specific mutations in urine vs peripheral blood (with special attention to AR-V7 and BRCA 1/2)
- response on therapy

## Study description

### Background summary

- detection of specific mutations in circulating tumor DNA in blood or urine
- in use for a personalised medicine of the patient: tailor-made treatment of the patient with the use of presence/absence of specific mutations as guidance

### Study objective

- special attention for the development and harmonization of the pre-analysis of liquid biopsy, for blood as well as urine, and next to this for ctDNA as well as ctRNA
- special attention for the detection of AR-V7 in blood and urine
- special attention for the detection of BRCA1/2 in blood and urine

Simultaneously also the development of a protocol for its detection in tissue

### Study design

Pre-analysis Isolation of cfDNA/RNA from blood and urine

- which type of matrix (blood, urine, saliva)
- which type of collection tube
- use of additive
- transport conditions primary sample

- storage conditions primary sample
- possible time till isolation
- centrifugation protocol
- storage conditions isolated ctDNA/RNA

Development molecular panel

- special attention to AR-V7 splice variant (detection in tissue, blood and urine)
- special attention to BRCA 1/2 (detection in tissue and blood)

### **Study burden and risks**

not applicable

## **Contacts**

### **Public**

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NL

### **Scientific**

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## **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

### **Age**

Adults (18-64 years)

Elderly (65 years and older)

## Inclusion criteria

- patients with metastasized castrate-resistant prostate carcinoma (mCRPC)
- patients with metastasized hormone-sensitive prostate carcinoma (mHSPC)

## Exclusion criteria

- no other malignancies
- no biopt of the primary tumor
- patients treated with radio-isotopes
- no informed consent

## Study design

### Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

### Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	29-06-2020
Enrollment:	100
Type:	Actual

## Ethics review

Approved WMO	
Date:	12-02-2020
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
CCMO	NL68319.096.20