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...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Renal and urinary tract neoplasms malignant and unspecified
Study type	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 de absence/presence of specific mutations in blood vs

primary tumor (with special attention to AR-V7 and BRCA 1/2)

- response on therapie

Secondary outcome

- relation between de absence/presence of specific mutations in urine vs

peripheral blood (with special attention to AR-V7 and BRCA 1/2)

- response on therapie

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 additiative
- 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

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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 prmary 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

Review commission: METC Z: Zuyderland-Zuyd (Heerlen)

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