Collection of body tissues and fluids for a biobank for prostate cancer.

Published: 19-09-2011
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Primary Objective: Establishment of an extensive PCa biobank for blood, urine, prostate tissue, lymph node tissue, and metastatic tissue in combination with clinical data, which can be used for future PCa research.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Reproductive neoplasms male malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON45185

Source
ToetsingOnline

Brief title
Prostate Cancer Biobank

Condition

- Reproductive neoplasms male malignant and unspecified
- Prostatic disorders (excl infections and inflammations)

Synonym
Prostate cancer, prostate carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Biobank, Future research, Prostate cancer

Outcome measures

Primary outcome

Establishment of an extensive PCa biobank which can be used for future PCa

research.

Secondary outcome

Not applicable.

Study description

Background summary

A major drawback of the standard diagnostic tools for PCa is the detection of small non-aggressive or non-life threatening cancers, leading to overdiagnosis and overtreatment, as well as the detection of tumours that are too advanced to cure. Currently, there are no blood or urine markers available for the prognosis of PCa at the time of early disease stages apart from PSA.

Improved diagnostic and prognostic markers are required that can discriminate men with clinically irrelevant PCa, curable PCa, or life threatening PCa. For this purpose we want to collect various body tissues and fluids from male patients with (the suspicion of) prostate cancer visiting the (outpatient) clinic of the Department of Urology.

Study objective

Primary Objective:
Establishment of an extensive PCa biobank for blood, urine, prostate tissue, lymph node tissue, and metastatic tissue in combination with clinical data, which can be used for future PCa research.

Study design

This study is a prospective observational study.

Study burden and risks

The biobank will be composed of blood, urine, prostate tissue, lymph node tissue, and metastatic tissue. Blood collection will preferably take place combined with a venepuncture done as standard of care to minimise patient burden. Urine will be collected after DRE (digital rectal examination) of the prostate. Urine collection will be combined as much as possible with a DRE of the prostate done as standard of care to minimise patient burden. Urine collection will only take place in patients in whom the prostate has not been surgically removed.

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

- Men >= 18 years.
- Patients with (the suspicion of) prostate cancer visiting the Department of Urology for standard care.
- Mentally and physically able to participate.
- Enough knowledge of the Dutch language to understand the informed consent form.
- Written informed consent.

Exclusion criteria

- Known HIV-infection or other serious infectious disease which can be transferred by one of the biomaterials.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	07-09-2012
Enrollment:	1000
Type:	Actual

Ethics review

Approved WMO

Date:	19-09-2011
Application type:	First submission

Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	12-07-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	16-05-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL33818.078.11