Prostate Cancer Molecular Medicine: Transition Grant 2015 (ProCaMolMed)

Published: 08-10-2015
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To validate two novel genomic biomarkers that provide information with respect to the presence of PCa, disease aggressiveness, and progression towards recurrent and metastatic disease.

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

Summary

ID

NL-OMON42675

Source
ToetsingOnline

Brief title
ProCaMolMed

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 Economische Zaken (via CTMM)

Intervention

Keyword: Biorepository, Diagnosis and therapeutic decision making, Prostate Cancer, Validation genomic biomarkers QUATTRO and PPI

Outcome measures

Primary outcome

- Predictive value of the novel genomic biomarker QUATTRO assessed in urine for detecting relevant cancer in a diagnostic prostate biopsy.

- Predictive value of the novel genomic biomarkers QUATTRO assessed in urine and PPI assessed in a biopsy for detecting relevant cancer in a RP specimen.

- Combined predictive value of the novel genomic biomarkers QUATTRO and PPI with MRI and histological biopsy markers for detecting relevant cancer in a RP specimen.

Secondary outcome

- Modelled QUATTO and PPI data in decision support tools for prostate cancer.

- Outcome on between-sites variability of the performance of the QUATTRO and PPI assays.

Study description

Background summary

Prostate cancer (PCa) is the most frequent non-cutaneous cancer in men. To prevent over-treatment in localized disease prognostic markers are needed. Since metastasized disease is always eventually lethal, prognostic and predictive markers and new therapeutic targets need study. The QUATTRO and PPI markers developed in Prostate Cancer Molecular Medicine (PCMM) can contribute as solutions for this clinical need and will be tested in this project.

Study objective

To validate two novel genomic biomarkers that provide information with respect to the presence of PCa, disease aggressiveness, and progression towards recurrent and metastatic disease.

Study design

Retrospective and prospective material sampling and documentation of clearly defined groups of patients suspicious for PCa and PCa patients.

Study burden and risks

Per patient additional serum and urine samples will be obtained once for biobanking on top of the clinical diagnostic routine including MRI. MRI studies of the prostate are performed in patients for assessment of men with increased risk for PCa according to the Rotterdam Prostate Cancer Risk Calculator (RPCRC, www.prostatecancer-riskcalculator.com). Improved imaging may benefit the patient, e.g. for surgeons preference how to perform steps during a radical prostatectomy (RP). The marker analysis will most likely not be of benefit to the participating patients since results will be expected to become available only after a few years.

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

Retrospective cohort
- Participants of Group 1 and/or 2 in PCMM.
- Obtained informed consent in PCMM.;Prospective cohort
- Men >= 18 years.
- Planned to undergo prostate biopsies according to standard practice.
- Signed informed consent.

Exclusion criteria

Prospective cohort
- Documented acute prostatitis or urinary tract infections within 8 weeks prior to inclusion.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-09-2016
Enrollment:	525
Type:	Actual

Ethics review

Approved WMO Date:	08-10-2015
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	21-04-2016
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	NL53610.078.15