

# Prostate Cancer Molecular Medicine: Transition Grant 2015 (ProCaMolMed)

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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.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Reproductive neoplasms male malignant and unspecified
<b>Study type</b>	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 QUATTRO 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](http://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**

### **Public**

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### **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

Retrospective cohort

- Participants of Group 1 and/or 2 in PCMM.
- Obtained informed consent in PCMM.;Prospective cohort
- Men  $\geq$  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**

CCMO

**ID**

NL53610.078.15