# Genomic based risk stratification in prostate cancer screening.

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Our goals are to collect blood from men randomized to the intervention arm of the Dutch part of the European Randomised study of Screening for Prostate Cancer (ERSPC) and actually screened (www.erspc.org, N=19.970, METC 138.741/1994/152). With the...

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

## Summary

### ID

NL-OMON37676

**Source**
ToetsingOnline

**Brief title**
ERSPC 2012/DNA

### 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:** ERSPC, Genomics, Prostate cancer screening, Risk stratification

## Outcome measures

### Primary outcome

SNPs profiling of 110 known SNPs and relate those to the available follow-up

data containing information of prostate cancer detection, treatment,

progression and casus specific death.

### Secondary outcome

Assess the possibilities to enhance existing risk stratification tools with

genomic based information.

# Study description

### Background summary

Screening for prostate cancer (PC) can reduce the suffering from metastatic disease and disease specific mortality. The applied Prostate Specific Antigen (PSA) based screening algorithm has however major drawbacks, resulting in a heavily debated healthcare conundrum. Recent advances in genomic research have made it possible to identify genomic based biomarkers for PC. These markers are easy to measure and stable over time. The current challenge now is not only to identify biomarkers but to validate these in wellcharacterized study cohorts.

### Study objective

Our goals are to collect blood from men randomized to the intervention arm of the Dutch part of the European Randomised study of Screening for Prostate Cancer (ERSPC) and actually screened (www.erspc.org, N=19.970, METC 138.741/1994/152). With the isolated DNA we will perform profiling of established diagnostic and prognostic PC single nucleotide polymorphisms (SNPs).

### Study design

This is an observational study.

### Study burden and risks

Participants in this study have no benefit form participation in the trial.
This is acceptable as the only study procedure is one blood withdrawal which is associated with very low risks.

## 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 randomised to the screening arm of ERSPC Rotterdam
- Signed informed consent

### Exclusion criteria

None

## Study design

### Design

**Study type:** Observational invasive

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

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 15-08-2013 |
| Enrollment: | 15000 |
| Type: | Actual |

## Ethics review

Approved WMO

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|---|---|
| Date: | 12-11-2012 |
| Application type: | First submission |
| 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 | NL39913.078.12 |