Genomic based risk stratification in prostate cancer screening.

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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

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

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