Tailored treatment of prostate cancer by biomarkers: PROCABIO

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Reproductive and genitourinary neoplasms gender unspecified NEC
Study type	Observational invasive

Summary

ID

NL-OMON33361

Source
ToetsingOnline

Brief title
PROCABIO

Condition

- Reproductive and genitourinary neoplasms gender unspecified NEC
- 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,GenProbe

Intervention

Keyword: Active surveillance, Biomarkers, Prostate cancer

Outcome measures

Primary outcome

Results of the analysis of the candidate biomarkers in the appropriate type of

sample in the patient sample sets from all clinical centres.

Secondary outcome

N.a.

Study description

Background summary

There are several genomic, proteomic and molecular pathology biomarkers for prostate cancer in development in commercial and in academic research laboratories that may have the potential to improve identification of indolent prostate cancer. Importantly, they may also be indicators of disease progression during active surveillance. New technological developments allow for the analysis of a considerable number of biomarkers simultaneously in a standard set of clinically relevant biomaterials. The PROCABIO (Tailored treatment of PROstate CAncer by BIOmarkers) project provides the unique opportunity to translate a broad range of the most promising biomarkers for prostate cancer that are currently looked upon by the industry as well as the academic institutes being of interest to the clinical setting of active surveillance.

Study objective

The following objectives have been defined for PROCABIO:
1. Integration of biomarkers in an updated and improved model for the prediction of indolent prostate cancer.
2. Integration of biomarkers in the development of guidelines for efficient strategies for active surveillance as a treatment
for indolent prostate cancer.
3. Delivery of validated biomarker tools that are easily applicable for high throughput use in clinical and screening settings.
4. Establishment of the overall acceptance of active surveillance as a

treatment modality for indolent prostate cancer by informing all stakeholders, including patients, clinicians, scientists and policy makers.

Study design

Observational study.

Study burden and risks

The risk of health damage caused by trial participation is negligible.

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

Patients who decide to participate in PRIAS or are participating in PRIAS for less than 2 years are eligible. The inclusion criteria for PRIAS are the following:
1. Histologically proven adenocarcinoma of the prostate
2. Men should be fit for curative treatment
3. PSA-level at diagnosis <= 10 ng/mL
4. PSA density (PSA D) less than 0,2
5. Clinical stage T1C or T2
6. Adequate biopsy sampling (see 'biopsy protocol')
7. Gleason score 3+3=6
8. One or 2 biopsy cores invaded with prostate cancer
9. Participants must be willing to attend the follow-up visits

Exclusion criteria

The exclusion criteria for PRIAS are the following:
1. Men who can not or do not want to be irradiated or operated
2. A former therapy for prostate cancer

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):	02-02-2010
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	26-03-2009
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	12-11-2009
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	NL26611.078.09