Detecting prostate cancer by the intracellular presence of prostate-specific antigen in macrophages, detected in peripheral blood samples by a flow cytometric technique.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Renal and urinary tract neoplasms malignant and unspecified
Study type	Observational non invasive

Summary

ID

NL-OMON37430

Source
ToetsingOnline

Brief title
Intracellular PSA in activated macrophages

Condition

- Renal and urinary tract neoplasms malignant and unspecified

Synonym
benign prostate hypertrophia, prostate carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Atrium Medisch Centrum
Source(s) of monetary or material Support: n.v.t.

Intervention

Keyword: flow cytometry, proinflammatory monocytes, prostate carcinoma, PSA

Outcome measures

Primary outcome

Detecting prostate cancer by the intracellular presence of prostate-specific

antigen in macrophages, detected in peripheral blood samples by a flow

cytometric technique.

Secondary outcome

Not applicable

Study description

Background summary

Prostate cancer, besides lung cancer, is the most common cancer in men. In the Netherlands prostate cancer has an incidence of approximately 6.61 per 1,000 men per year (NKR 2007). Given this, more than 9800 new patients will be diagnosed with prostate cancer in the Netherlands.
Using prostate-speci*c antigen (PSA), a widely used serum marker for prostate cancer, the incidence of this diagnosis has been increasing. PSA is a protein formed by the normal and abnormal prostate, which is normally present in the blood to a limited extent. It is assumed this marker is a measure of the activity of certain parts of the prostate tissue.
However, PSA is not in all forms of prostate cancer elevated and elevated PSA is not always associated with cancer. It is also known that, with increasing age, the content of PSA in the blood can increase without finding abnormalities of the prostate. Equally, the PSA can be elevated in both prostatitis and benign prostatic hyperplasia (BPH).
PSA has a limited specificity in prostate cancer detection. Patients with serum PSA levels > 4 ng/mL will undergo prostate biopsy for further histological examination. This is often a stressful and painful procedure for the patient.

Up to 75% of men who undergo prostate biopsy because of PSA values between 4-10 mg / l do not have prostate cancer. Often re-biopsies are performed.

Study objective

At the Atrium Medical Center Heerlen, in 2005 a study has been initiated with the aim of developing a new diagnostic tool for patients with prostate carcinoma. By using flow cytometry, PSA can be measured in activated monocytes, naming macrophages. These monocytes migrate into (cancer)tissues in which they differentiate into functionally distinct macrophages. Afterwards, when they have incorporated debris and possibly tumour tissue by active phagocytosis, they will turn back into the bloodstream.
This new diagnostic tool is able to detect tumor tissue in activated macrophages (imPSA, intracellular macrophage PSA) in the peripheral blood of patients with prostate carcinoma. It is able to produce a significant difference between BPH and prostate carcinoma.
In recent years a lot of effort is invested in improving this technique. That study is part of this effort. Blood samples will be taken of men with complaints of their prostate when visiting the outpatient department of Urology. These samples will be tested for imPSA by flow cytometry.

Objective of the study:
To study and evaluate whether PSA in activated macrophages in peripheral blood samples of patients with prostate cancer is a more specific and sensitive marker for differentiating between benign and malignant prostate diseases than the conventional serum total PSA or not.

Study design

Blood samples in EDTA tubes will be collected from every patient. These will be immunocytochemical stained, after which the mononuclear cells will be isolated and further investigated with monoclonal antibodies (CD14 and CD16) using a standard protocol.
After this, these samples will be stained intracellular with a PSA antibody.
Finally the samples will be flow cytometric analysed.

Blood samples will be taken by a medical student, BSc.

Statistical analysis will be performed using SPSS/GraphPad Prism/Excell.

Study burden and risks

While taking blood samples, in rare cases, a serious adverse event (SAE) can take place. This can be a phlebitis or a venous bleeding. Worst case scenario will be a shock; only this event will a part of the SAE-regulation of the CCMO.

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

- all men, who visit the department of urology with prostate complaints (in the period april 2012-july 2012)
- by which a needle-biopsy is performed for histopathologic examination
- signed informed consent

Exclusion criteria

- proven prostate pathology

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2013
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO

Date:	21-03-2012
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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	NL39773.096.12