Clinical Evaluation of the PCA3 Assay in Men Requiring a Repeat Biopsy

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To determine the performance characteristics (specificity, sensitivity, and positive and negative predictive values) of the PCA3 Assay using prostate biopsy as the reference method in men who are scheduled for a repeat prostate biopsy after a...

Ethical review	Approved WMO
Status	Pending
Health condition type	Prostatic disorders (excl infections and inflammations)
Study type	Observational invasive

Summary

ID

NL-OMON29886

Source
ToetsingOnline

Brief title
Clinical Evaluation of the PCA3 Assay in Men Requiring a Repeat Biopsy

Condition

- Prostatic disorders (excl infections and inflammations)

Synonym
prostate cancer / adenocarcinoma of the prostate

Research involving
Human

Sponsors and support

Primary sponsor: Gen-Probe Incorporated, European Office
Source(s) of monetary or material Support: Gen-Probe Incorporated

Intervention

Keyword: diagnosis, human, prostate cancer antigen 3, prostatic neoplasms, urine

Outcome measures

Primary outcome

The performance characteristics (specificity, sensitivity, and positive and

negative predictive values) of the PCA3 Assay using prostate biopsy as the

reference method.

Secondary outcome

Not applicable

Study description

Background summary

The 2 most common methods used for prostate cancer screening are the DRE and tests to measure total serum PSA (serum PSA test). The use of the serum PSA test has resulted in the earlier diagnosis of prostate cancer compared to other methods, such as the DRE. Traditionally, a biopsy is performed when the serum PSA value is greater than 4.0 ng/mL. However, an increasing number of physicians use a cutoff value of 2.5 ng/mL to determine if a biopsy is needed; this cutoff is often used for younger men. Although the number of unnecessary biopsies increases by lowering the cutoff value, the number of organconfined cancers increases, which improves patient outcomes. Although the serum PSA test is sensitive for detecting prostate cancer, the majority (>60%) of men with elevated serum PSA levels will be negative for cancer because serum PSA levels can be elevated in men with noncancerous prostate disease, such as benign prostatic hyperplasia (BPH) or prostatitis. Patient management is unclear for men who continue to have elevated serum PSA levels after having a negative biopsy result because a negative biopsy result is inconclusive for the absence of cancer. Approximately 20% of men with serum PSA levels of 4.0 ng/mL or greater will have a positive biopsy result at follow-up due to a missed cancer diagnosis during the previous biopsy (ie, false negative biopsy result) or due to the development of cancer over time. However, since most men with elevated serum PSA levels will be negative for cancer at follow-up, tests with better specificity are needed to help guide repeat biopsy decisions and to reduce unnecessary procedures and anxiety. PCA3 has shown promise as a diagnostic tool

in prostate cancer, particularly because PCA3 has a higher specificity than the serum PSA test.

Study objective

To determine the performance characteristics (specificity, sensitivity, and positive and negative predictive values) of the PCA3 Assay using prostate biopsy as the reference method in men who are scheduled for a repeat prostate biopsy after a previous negative prostate biopsy.

Study design

A nonpivotal, prospective, multi-center clinical study will be conducted. Male subjects who are scheduled for a repeat prostate biopsy after a previous negative prostate biopsy will be enrolled. Once enrolled into the study, blood and urine specimens will be collected. Blood will be tested with assays that measure total serum PSA (serum PSA test) and free serum PSA (free PSA test). A first-catch urine sample will be collected following a special, standardized DRE performed by an experienced medical practitioner. The urine sample will be processed and tested with the PCA3 Assay. Biopsies will be performed by an experienced medical practitioner per the site*s normal procedure. Biopsy specimens will be evaluated by pathologists at the clinical site. PCA3 Assay results will be compared to biopsy results to determine the assay*s performance characteristics (specificity, sensitivity, positive and negative predictive values).

Study burden and risks

One single bloodsample (3.5 mL) will be collected from each subject. This is a lot less than the amount of blood that is drawn at a blood donation. Subsequently, each subject will undergo a special, standardized DRE, instead of a normal DRE. Therafter, a first-catch urine sample will be collected. The special, standardized DRE is harmless and is regarded as 'well tolerable'. The extent of the burden associated with participation therefore is minimal.

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

The subject*s last prostate biopsy must have been performed greater than 3 months prior to enrollment and must have been negative for cancer. The previous biopsy must have included at least 6 cores and the pathology report must be available.

Exclusion criteria

• More than 2 previous prostate biopsies
• Use of finasteride, dutasteride, leuprolide acetate, or other medications or hormones (within the past 3 months) that are known to affect serum PSA levels
• Symptoms of urinary tract infection (including prostatitis) at the time of enrollment
• History of prostate cancer
• History of invasive treatments for BPH or lower urinary tract symptoms (LUTS), eg, transurethral resection of the prostate (TURP), heat, laser, or ultrasound treatments in the last 6 months

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-08-2006
Enrollment:	60
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL13132.091.06