PILOT-STUDY FOR PROFILING PSA GLYCOSYLATION AS PUTATIVE PROSTATE CANCER BIOMARKER BY HIGH RESOLUTION NATIVE MASS SPECTROMETRY

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To evaluate and compare PSA-glycosylation patterns in semen of prostate cancer patients and healthy controls.To correlate PSA-glycosylation patterns in semen with pathological tumour stage and Gleason grade in prostate cancer patients.

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

Summary

ID

NL-OMON42143

Source
ToetsingOnline

Brief title
Profiling PSA glycosylation

Condition

- Reproductive neoplasms male malignant and unspecified

Synonym
Prostate Cancer

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Biomarker, Glycosylation, Prostate, PSA

Outcome measures

Primary outcome

- PSA-glycosylation patterns (finger-prints) for prostate cancer versus normal

controls

- Correlation between PSA-glycosylation patterns and Gleason grade/tumour stage

(clinical and pathological)

Secondary outcome

Correlation between PSA-glycosylation patterns and PSA-level in serum

Study description

Background summary

Recently we have built up a workflow, which allows us to purify seminal PSA from individual donors, starting with a reasonably small amount (3-5 mL) of semen sample. Using an in-house developed high resolution native Mass Spectrometry platform, we are able to characterize intact PSA including its molecular heterogeneity, in a qualitative and quantitative manner. From these preliminary data we conclude that it is well-intentioned to apply this novel strategy on PCa samples, to detect the changes of glycosylation profiles at the intact PSA level. It has been hypothesized that PSA-glycosylation patterns in semen can be related to the presence of prostate cancer and these specific PSA-glycosylation patterns can be correlated with high-grade and high-risk prostate cancer.

Study objective

To evaluate and compare PSA-glycosylation patterns in semen of prostate cancer

patients and healthy controls.
To correlate PSA-glycosylation patterns in semen with pathological tumour stage and Gleason grade in prostate cancer patients.

Study design

This is an observational study to analyse PSA-glycosylation patterns in the semen of prostate cancer patients and to compare these outcomes with healthy controls. All patients with biopsy-proven prostate cancer, who are being scheduled for robot-assisted laparoscopic prostatectomy may be included in this study. Healthy controls will be recruited from the outpatient clinic of the Department of Urology. The healthy controls will be patients with lower urinary symptoms (LUTS), a non-suspicious serum PSA-level (PSA < 3.0 ng/ml) and no suspicion for prostate cancer on digital rectal examination and transrectal ultrasound.

Study burden and risks

The risks of participation in this study are negligible. The benefit may be that by determining these PSA-glycosylation patterns in the semen, prostate cancer may be detected at an earlier stage. The PSA-glycosylation may also be indicative for aggressiveness of the disease, thus guiding clinical decision-making in prostate cancer.

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

Inclusion criteria for patients:
-Male gender
-Signed written informed consent
-Biopsy-proven prostate cancer, eligible for surgery
-Age 55 - 70 years
-Willing and able to collect semen;Inclusion criteria for controls:
-Male gender
-Visiting the outpatient clinic because of lower urinary tract symptoms (LUTS)
-Signed written informed consent
-Serum PSA < 3.0 ng/ml
-No suspicion for prostate cancer on digital rectal examination and transrectal ultrasound as judged by the urologist
-Willing and able to collect semen

Exclusion criteria

-Urinary tract infection

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-07-2015
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	01-04-2015
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL50841.041.15