Pilot study: performance of the Progensa PCA3 test in post-oxytocin urine specimens

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The primary objective is to determine the yield of prostate cells in the urine specimen after oxytocin nasal spray, using a urine specimen with no manipulation as a reference method.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Prostatic disorders (excl infections and inflammations)
Study type	Interventional

Summary

ID

NL-OMON36233

Source
ToetsingOnline

Brief title
Pilot: Efficacy of Progensa PCA3 test in post-oxytocin urine

Condition

- Prostatic disorders (excl infections and inflammations)

Synonym
prostate cancer, prostate carcinoma

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Oxytocin, PCA3, Prostate Cancer

Outcome measures

Primary outcome

The main study parameter is to determine yield of prostate cells (PSA mRNA) in

the urine specimen collected after the oxytocin administration, compared to the

yield in the urine specimen collected before oxytocin administration.

Secondary outcome

Not applicable

Study description

Background summary

Prostate cancer (PCa) is the most frequent malignancy diagnosed in the Western male population. Although the routine use of serum prostate-specific antigen (PSA) testing has undoubtedly increased PCa detection, one of its main drawbacks has been its lack of specificity, which results in a high negative biopsy rate. Furthermore, there is objective indication that PSA-based (opportunistic) screening has led to the diagnosis of clinically insignificant prostate tumours, i.e. in the absence of screening these tumours would not have been diagnosed within the patient*s lifetime, which results in over-treatment.

PCA3 (Prostate CAncer gene 3) is a new prostate specific gene that is highly overexpressed in prostate cancer tissue. This gene was identified at the experimental urology laboratory in Nijmegen in 1999. Since 2006, the Progensa® PCA3-test is a clinically available urine test that is indicated to aid in the decision to take repeat prostate biopsies. Levels of PCA3 can be measured in the urine after digital rectal examination (DRE). A DRE is necessary to shed enough cells to provide informative specimens. The informative rate for specimens collected absent a DRE is low (75.9%), compared to 96,7% when a DRE is performed.

We hypothesize that oxytocin nasal spray can be used instead of a DRE to mobilize prostate cells into the urethra. Oxytocin nasal spray is used in the clinical setting to promote nursing. In several studies, oxytocin nasal spray

is used for the molecular analysis of nipple fluid for breast cancer screening. Oxytocin nasal spray increases the yield of nipple aspirate fluid by causing rhythmic contractions of the myoepithelial cells around the acini of the breast. In these studies, no oxytocin side-effects were reported. Embryologically, the prostate in the male may be viewed as corresponding to the uterus in the female. Oxytocin blood levels are increased during and after ejaculation in humans (Carmichael et al 1987); oxytocin is found to contract the prostate. If our hypothesis is correct, oxytocin could replace the DRE in the future to shed enough cells for PCA3 measurement.

Study objective

The primary objective is to determine the yield of prostate cells in the urine specimen after oxytocin nasal spray, using a urine specimen with no manipulation as a reference method.

Study design

A prospective pilot study will be conducted to determine the yield of prostate cells in urine collected before and after oxytocin nasal spray administration. Ten healthy male subjects will be included. Urine specimens without manipulation will be collected from all subjects. Subsequently, all subjects will be administered 4 IE (=1 spray) of oxytocin in both nostrils. 5 minutes after administration, subjects will provide again a urine specimen. The urine specimen will be processed and tested for the amount of PSA mRNA with the Progensa® PCA3-test at Laboratory Experimental Urology (RUNMC). PCA3 mRNA and the PCA3 score will not be measured.

Intervention

We will administer 4 IE (=1 spray) in each nostril of all subjects.

Study burden and risks

Both the risk and the burden of participation are minimal. No serious side effects of oxytocin nasal spray are reported. Side effects are seen only seldomly(>=1/10.000, <1/1.000): allergic skin reactions, headache and nausea. The burden is also minimal: administration of oxytocine and collect two urine samples.

Using the Progensa PCA3 Assay, only the amount of PSA mRNA will be measured .The amount of PCA3 mRNA will not be measured, thus the PCA3 score will not be calculated. Therefore, this study will not give any information about the health status/risk of having prostate cancer of the subjects.

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

healthy male subject
>= 18 years old

Exclusion criteria

history of prostate cancer
use of medication known to affect PSA level (eg. finasteride, dutasteride)
Symptoms of urinary tract infection

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-06-2011
Enrollment:	10
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Syntocinon nasal spray
Generic name:	Oxytocin nasal spray
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	14-01-2011
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	05-04-2011
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
EudraCT	EUCTR2010-024649-61-NL
CCMO	NL35254.091.11