Quantification of Contrast Enhanced Ultrasound (CEUS) in the detection of Prostate cancer.

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2.1 Primary objective: To improve PCa detection rate with quantification, compared with subjective CEUS interpretation and known numbers in literature. 2.2 Secondary objective: To compare quantification results with tumour differentiation grade (...

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

Summary

ID

NL-OMON36092

Source
ToetsingOnline

Brief title
CEUS before biopsy

Condition

- Renal and urinary tract neoplasms malignant and unspecified

Synonym
Prostate adenocarcinoma, Prostate cancer

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Stichting Cure for Cancer

Intervention

Keyword: CEUS, Prostate cancer, Quantification, TRUS

Outcome measures

Primary outcome

See objective

Secondary outcome

See objective

Study description

Background summary

With Contrast Enhanced UltraSound (CEUS) cancer induced neovascularisation can be visualised with the potential to improve ultrasound imaging for prostate cancer detection and localisation significantly. The past years numerous studies have been performed with CEUS, all basing their results on subjective judgement of the investigator. CEUS image interpretation is difficult and requires a well-trained expert. To overcome these difficulties CEUS quantification techniques can be of use. The techniques used in this protocol have been developed by the Technical University in Eindhoven (TU/e) and BRACCO, Geneva.

Study objective

2.1 Primary objective:
To improve PCa detection rate with quantification, compared with subjective CEUS interpretation and known numbers in literature.

2.2 Secondary objective:
To compare quantification results with tumour differentiation grade (Gleason score)

2.3 Presentation of the question:
- What is the difference in, for malignancy suspicious, areas between CEUS quantification and subjective interpretation in relation to the histological biopsy results?
- Is there a relation between Gleason score and quantification results?
- Is there an additional value for use of CEUS quantification in clinical

practice?

Study design

This study is a prospective in-vivo study in humans in which we perform a CEUS before taking systematic prostate biopsies. These patients are already scheduled for biopsy because of a raised Prostate-Specific Antigen (PSA) or abnormal Digital Rectal Examination (DRE). Afterwards a quantitative analysis of all CEUS data will be performed.

Study burden and risks

Benefits:
Normally, if no cancer is detected by systematic biopsies, when a suspicion for prostate cancer is still raised, the biopsies are repeated. Based on the quantification results determined after the first systematic biopsies, in this second session, the systematic biopsies can be optimal targeted in for malignancy suspicious lesions. In this way, cancer detection during the repeated biopsy session could increase.
If the results of the study show a correlation between quantification and the biopsy results, in the future this could open the way for targeted biopsies based on quantification techniques and therefore could decrease the number of biopsies with a better cancer detection. Therefore, this could decrease the burden for the patient and might improve prostate cancer treatment selection.

Risk assessment:
There is a small anticipated risk for participants. After use in thousands of patients, adverse events appear to be transient, mild and rare. The side effects mostly consist of transient alteration of taste, local pain at the injection site and facial of general flush. In rare cases allergic reaction to the contrast agent is described. (see 6).
Patients will be informed of the risk during intake, and it will be described in the study information.

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

- planned for prostate biopsy
- over 18 years old
- signed informed consent

Exclusion criteria

- acute prostatitis of urinary tract infection
- severe heart disease or recent onset of rhytmic disorders
- had prostate biopsy within 30 days

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	11-11-2011
Enrollment:	560
Type:	Actual

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL37231.018.11