CEUS targeted biopsies compared to mpMRI targeted and systematic biopsies for the detection of Prostate Cancer.

Published: 11-11-2015
Last updated: 16-04-2024

Primary objective: To compare the cancer detection rate of CEUS targeted biopsies with the cancer detection rate of mpMRI targeted and systematic biopsies. Secondary objective: To characterize the tumors detected by the different biopsy schemes in...

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

Summary

ID

NL-OMON44958

Source
ToetsingOnline

Brief title
Value of CEUS targeted biopsies in detection of PCa

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: KWF

Intervention

Keyword: CEUS, kwantificatie, Prostate cancer, Targeted biopsies

Outcome measures

Primary outcome

Prostate cancer detection rate.

Secondary outcome

Tumor differentiation grade (Gleason score).

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 (PCa) 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 in cooperation with the Eindhoven University of Technology (TU/e).

Study objective

Primary objective:

To compare the cancer detection rate of CEUS targeted biopsies with the cancer detection rate of mpMRI targeted and systematic biopsies.

Secondary objective:

To characterize the tumors detected by the different biopsy schemes in terms of Gleason score.

Study design

This study is a prospective in-vivo study in human patients. These patients are scheduled for prostate biopsy with systematic biopsies and mpMRI targeted

biopsies as standard of care due to elevated serum Prostate Specific Antigen (PSA) and/or abnormal digital rectal examination (DRE). For the purpose of this study, patients will undergo a CEUS imaging procedure through an additional infusion of a contrast agent next to the mpMRI imaging procedure. During the biopsy session, for the purpose of this study a maximum of 4 targeted CEUS biopsies will be taken from a max of 2 CEUS suspicious lesions by an experienced investigator blinded to mpMRI results and next to the mpMRI targeted biopsies and systematic biopsies. Afterwards the cancer detection rate and tumor differentiation grade of targeted biopsies will be compared with those of the systematic biopsies.

Study burden and risks

Benefits

Normally, if no cancer is detected by systematic biopsies and the suspicion for prostate cancer persists, biopsies are repeated. If cancer missed by these systematic biopsies is detected using CEUS dispersion imaging targeted biopsies the patients would benefit from it. Furthermore, an improved determination of the Gleason score by targeted biopsies might improve the selection of prostate cancer treatment.
If this study is successful in the future all patients undergoing biopsies will benefit from these results.

Risk assessment

There is a small anticipated risk for participants. After use in thousands of patients, adverse events to the ultrasound contrast agent 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 or general flush. In rare cases allergic reaction to the contrast agent is described. 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

- Scheduled for prostate biopsy
- Over 18 years
- Signed informed consent
- mpMRI data available

Exclusion criteria

- Has documented acute prostatitis or urinary tract infections
- History of any clinically evidence of cardiac right-to-left shunts
- Receives treatment that includes dobutamine
- Has severe pulmonary hypertension (pulmonary artery pressure >90 mmHg) or uncontrolled systemic hypertension or respiratory distress syndrome
- Has received a biopsy procedure within 30 days before admission into this study
- Has any medical condition or other circumstances which would significantly decrease the chances of obtaining reliable data, achieving study objectives, or completing the study
- Is incapable of understanding the language in which the information for the patient is given
- Has received a biopsy procedure at the AMC within a year before admission into this study

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-12-2015
Enrollment:	299
Type:	Actual

Ethics review

Approved WMO Date:	11-11-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-02-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-03-2019
Application type:	Amendment
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
ClinicalTrials.gov	NCT01481441
CCMO	NL52851.018.15