Prostate cancer diagnosis by multiparametric ultrasound

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The primary objective is to collect high-quality 3D mpUS and histology data, to train and improve the classifier algorithm with the goal of achieving an accurate ultrasound imaging tool for the detection of clinically significant prostate cancer.

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

Summary

ID

NL-OMON54171

Source
ToetsingOnline

Brief title
mpUS for PCa detection

Condition

- Reproductive neoplasms male malignant and unspecified

Synonym
Prostate cancer, prostatic adenocarcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: National Institutes of Health (NIH)

Intervention

Keyword: Artificial intelligence, Diagnostics, Multiparametric ultrasound, Prostate cancer

Outcome measures

Primary outcome

For the primary objective, training and improving the algorithm, we focus on

• Gleason/Grade group scoring based on histology. Using histology as the reference standard we will optimize the accuracy of the algorithm in differentiating between benign tissue and various grades of malignancy.

• Localization and size of lesions at full-gland histology. Correlation in tumour size and location will be optimized between 3D mpUS findings and histology of the full gland.

Secondary outcome

For the secondary objective, preliminary assessment of the performance of 3D mpUS, we will evaluate the following endpoints:

• Among all clinically significant detected cancers confirmed by histology, we will calculate the proportion of these cancers that would have been detected by 3D mpUS. This sensitivity of 3D mpUS will be calculated for patients undergoing radical prostatectomy. The number of false positive findings by 3D mpUS both as an absolute count and expressed as a mean rate per patient.

• The concordance in the detection and grading of abnormalities between mpMRI and 3D mpUS by examining the frequency and type of disagreements and calculating the kappa statistic.

Study description

Background summary

Current imaging techniques for the detection and grading of prostate cancer are imperfect, leading to unnecessary biopsies, suboptimal treatment decisions and missed clinically significant cancers. We hypothesize that computer assisted analysis of 3D multiparametric ultrasound (mpUS) images can accurately detect, grade and localize prostate cancer. 3D mpUS may then become a more cost-effective and more streamlined imaging strategy than the current standard: mpMRI.

Study objective

The primary objective is to collect high-quality 3D mpUS and histology data, to train and improve the classifier algorithm with the goal of achieving an accurate ultrasound imaging tool for the detection of clinically significant prostate cancer.

Study design

This is a prospective study in men with confirmed prostate cancer who are scheduled to undergo a radical prostatectomy. Prior to radical prostatectomy, 3D mpUS imaging will be performed. The ultrasound images will be analyzed and used for algorithm training using the prostatecomy specimens as gold standard. The outcome of the 3D mpUS analysis and the additional pathology evaluation are for research purposes only and will not interfere with standard patient care.

Study burden and risks

To obtain 3D mpUS images, patients will undergo standard transrectal ultrasound after the administration of ultrasound contrast intravenously. To obtain 3D mpUS images from patients scheduled for radical prostatectomy an additional visit to the including center is necessary. The additional visit and transrectal ultrasound can be experienced as a significant burden for the patient. Study participants will be informed on this additional burden.
The administration of ultrasound contrast is and will lead to an additional five minutes of examination time. There is a small anticipated risk associated with the use of ultrasound contrast for participants. After use in millions of patients in various types of ultrasound examinations, adverse events to the ultrasound contrast agent appear to be transient, mild and rare. The side effects of the ultrasound contrast agent mostly consist of transient alteration of taste, local pain at the injection site and facial or general flush. In some cases, an allergic reaction is described that is usually mild. Patients will be informed of the risk during intake, and it will be described in the patient

information file. The 3D mpUS images will not be used for making management decisions, consequently there will be no safety issues due to changes in standard care, but also no direct benefit for patients participating in the study.

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

Men >=18 years with confirmed prostate cancer scheduled for radical prostatectomy

Exclusion criteria

- No mpMRI performed prior to prostate biopsy or radical prostatectomy
- A history of chemotherapy for PCa or currently being treated with chemotherapy for PCa.
- A patient history that includes any of the following prostate related interventions:
o Brachytherapy or external radiotherapy for PCa;
o Focal therapy for prostate cancer;
o Prostate biopsy within the last 30 days.
- Hormonal therapy for prostate cancer within the last six months
- A patient history with a cardiac right to left shunt.
- Current treatment with dobutamine
- Known severe pulmonary hypertension (pulmonary artery pressure >90 mmHg), uncontrolled systemic hypertension or respiratory distress syndrome
- Incapable of understanding the language in which the patient information is given.
- Allergic reaction to previous ultrasound contrast administration.

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):	31-07-2024
Enrollment:	25
Type:	Actual

Medical products/devices used

Generic name:	Algorithm for prostate cancer diagnosis based on multiparametric ultrasound

Registration:	No

Ethics review

Approved WMO Date:	31-07-2023
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-02-2024
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
CCMO	NL78493.018.23