Clinical validation of transrectal multiparametric ultrasound imaging strategy (PCaVision) for the detection of clinically significant prostate cancer: a European head-to-head comparison with the MRI-based strategy in primary diagnosis and in an active surveillance population

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

Summary

ID

NL-OMON57088

Source
ToetsingOnline

Brief title
PCaVision II

Condition

- Prostatic disorders (excl infections and inflammations)

Synonym
prostate cancer, Prostate carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: Angiogenesis Analytics

Intervention

Keyword: Artificial intelligence, Magnetic resonance imaging, Multiparametric ultrasound, Prostate cancer

Outcome measures

Primary outcome

The primary endpoint of this study is clinically significant (GG >=2) PCa. The detection rate of this endpoint in any core for each biopsy strategy will be assessed to demonstrate the non-inferiority of PCaVision targeted biopsy strategy in comparison with MRI targeted biopsy strategy. The detection rate is expressed with patients as the unit of analysis. The primary endpoint will be determined for two (separately powered) cohorts (1) biopsy-naïve or prior negative and (2) patients in active surveillance

Secondary outcome

Secondary endpoints:

· proportion of men in whom targeted biopsies could have been safely omitted in the PCaVision pathway compared to the MRI pathway. This is defined as the number of men in whom no lesions for target biopsies have been identified by PCaVision while no clinically significant cancer is detected in either MRI targeted biopsies or systematic biopsies. The combined findings of all types of

biopsies will serve as the reference standard to define *safe*.

· same diagnostic accuracy analyses as described in the primary endpoint for different definitions of the target condition. This includes: (i) ISUP >= 3 in any of the biopsy cores taken from a lesion; (ii) ISUP >= 2 with cribriform growth and/or intraductal carcinoma (CR/IDC) in any of the biopsy cores taken from a lesion; (iii) ISUP = 1.

· comparison of the number of men in whom the PCaVision pathway provided insufficient quality images or targeted biopsies with the number of men with insufficient quality MRI images or target biopsies in the MRI pathway.

· Detection rate of clinically significant PCa (GG >=2) for a different patient subpopulations. This includes (i) patients under 5-ARI treatment for at least 3 months; (ii) patients with previous prostate surgeries for LUTS; (iii) biopsy naïve and prior negative without taking into account patients under 5-ARI treatment for at least 3 months and those who previously underwent prostate surgery, (iv) patients in active surveillance without taking into account patients under 5-ARI treatment for at least 3 months and those who previously underwent prostate surgery.

Study description

Background summary

Current imaging techniques for the detection and grading of prostate cancer are imperfect, which can lead to unnecessary biopsies, suboptimal treatment, and missed clinically significant cancers. We hypothesize that computer analysis (PCaVision) of 3D multiparametric ultrasound can accurately detect, localize, and assess the aggressiveness of prostate cancer. 3D multiparametric ultrasound could provide a more cost-effective and streamlined imaging technique compared

to the current standard: MRI.

Study objective

The primary objective is to demonstrate non-inferiority of the detection rate of clinically significant prostate cancer (defined as GG>=2) in targeted biopsies based on PGaVision imaging (PCaVision pathway) in comparison with the detection rate of clinically significant cancer in targeted biopsies based on MRI (MRI pathway).

Study design

This study is a prospective, multicenter diagnostic accuracy study with a fully paired design in men suspected of prostate cancer.
In summary, all patients will undergo imaging using MRI and PCaVision during which suspicious lesions will be identified based on each imaging technique independently with readers being blinded for the results of the other imaging technique. In addition, biopsies can be performed. What biopsie strategy is performed is based on the imaging results and local standard of care. In case of a suspect lesion on imaging targeted biopsies will be performed. Local standard might dictate that these targeted biopsies are supplemented by systematic biopsies, this won't be part of the study protocol. In case of negative imaging, biopsies can be omitted or systematic biopsies can be performed. This also depends on the local standard of care and is not part of the study protocol.
MRI targeted 3-core biopsy per lesion (maximum of 2 lesions) and/or a PCaVision targeted 3-core biopsy (maximum of 2 lesions) will be performed by a second physician if suspicious lesions have been identified based on imaging. lf lesions have been identified with both PCaVision and MRI in the same patient, the order of the targeted biopsies will be randomized. Histological examination of targeted biopsies will be performed to determine presence of clinically significant prostate cancer.

Intervention

All patients undergo 3D mpUS using PcaVision and MRI. Suspicious lesions will be identified based on each imaging technique independently. This will be followed by a single biopsy session in which the following types of biopsies might be performed.
hat biopsie strategy is performed is based on the imaging results and local standard of care. In case of a suspect lesion on imaging targeted biopsies will be performed. Local standard might dictate that these targeted biopsies are supplemented by systematic biopsies, this won't be part of the study protocol. In case of negative imaging, biopsies can be omitted or systematic biopsies can be performed. This also depends on the local standard of care and is not part of the study protocol.

A MRI targeted biopsy and/or a PCaVision targeted biopsy will be performed if suspicious lesions have been identified based on imaging. Per imaging technique, the following approach is followed. When 1 suspicious lesion has been identified, 3 targeted biopsies will be taken. When 2 lesions have been identified, 3 targeted biopsies will be taken per lesion, so 6 biopsies in total. In case 3 or more suspicious lesions have been found, 2 lesions will be selected based on: (1) PI-RADS and (2) size for MRI, and (1) severity indication and (2) size for PCaVision. Consecutively, 3 targeted biopsies will be taken from these 2 selected lesions.
So, the maximum number of targeted biopsies per imaging technique is 6, and the maximum number of biopsies per patient is 24 including 12 systematic biopsies.
If lesions have been identified with both PCaVision and MRI in the same patient, the order of the targeted biopsies will be randomized. All biopsies (systematic and targeted) will be performed in a single session.

Study burden and risks

- Possible additional hospital visit as for recording the 3D mpUS
- There is a small risk associated with the use of ultrasound contrast medium for participants. After using contrast medium in millions of patients in various types of ultrasound examinations, side effects appear to be rare and mostly mild. Possible side effects are: change in taste, local pain at the injection site and erythema of the face or body. In some cases, an allergie reaction has been described, which is usually mild.
- Doing a 3D mpUS can lead to taking extra prostate biopsies

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

· be male
· have an age of 18 years or older
· be scheduled for evaluation by prostate MRI based on a suspicious DRE and/or elevated serum PSA or as part of active surveillance follow-up
· have signed informed consent

Exclusion criteria

· active (urinary tract) infection or prostatitis
· a patient history with a cardiac right-to-left shunt.
· allergic to sulphur hexafluoride or any of the other ingredients of the ultrasound contrast agent SonoVue
· current treatment with dobutamine
· known severe pulmonary hypertension (pulmonary artery pressure >90 mmHg), uncontrolled systemic hypertension or respiratory distress syndrome
· any (further) contraindication to undergo MRI or 3D mpUS imaging
· incapable of understanding the language in which the patient information is given.
· previous treatment of focal therapy for prostate cancer

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2025
Enrollment:	20
Type:	Anticipated

Medical products/devices used

Generic name:	PCaVision
Registration:	No

Ethics review

Approved WMO

Date:	17-10-2024
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	NL87353.000.24