The role of targeted MRI-ultrasound fusion biopsies of the prostate in patients suspected for prostate cancer

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The objective of this study is to improve the treatment of prostate cancer. By more accurately diagnosing both clinically significant and insignificant prostate cancer, treatment strategies will improve. This accounts for active treatment like...

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-OMON44626

Source
ToetsingOnline

Brief title
ProMES study (prostate biopsies using MR-Ultrasound fusion study)

Condition

- Renal and urinary tract neoplasms malignant and unspecified

Synonym
malignant neoplasm of the prostate, Prostate cancer

Research involving
Human

Sponsors and support

Primary sponsor: Isala Klinieken
Source(s) of monetary or material Support: I&W fonds Isala klinieken

Intervention

Keyword: MRI-ultrasound fusion biopsies, Prostate biopsies, Prostate cancer, Targeted biopsies

Outcome measures

Primary outcome

All found prostate cancers

Secondary outcome

Classification of the found prostate cancers

The amount of patients eligible for Active Surveillance

Study description

Background summary

Prostate cancer (PCa) is the most commons cancer among men over 40 years. Standard diagnostics for men suspected to have prostate cancer encompass 10-12 ultrasound-guided random biopsies of the prostate in a fixed manner. This method is known to have several shortcomings such as detection of clinically insignificant cancers, false-negative results and the need for repeated biopsies in case of negative results. Multi-parametric magnetic resonance imaging (MP-MRI) of the prostate is an evolving imaging method that allows accurate visualization of prostate cancer. By fusing these images with transrectal ultrasound images, targeted biopsies can be performed. These MRI-ultrasound fusion biopsies are reported to diagnose more clinically relevant prostate cancers (with a higher Gleason score). Therefore MRI-ultrasound fusion biopsies have the potential to reduce overtreatment of patients. However, random biopsies are shown to diagnose more cases of prostate cancer and optimal clinical application of targeted biopsies has not yet been determined. Also inclusion criteria for Active Surveillance have not yet been determined. Unfortunately, studies until now have not been performed with uniform definitions according to EAU guidelines or have not applied de PIRADS classification system. Furthermore, negative MP-MRI ruled out prostate biopsies. Therefore, a good comparison between MP-MRI, MRI-ultrasound fusion biopsies and random biopsies has not been performed yet.

It is clear that a more targeted approach is necessary to improve detection of clinically significant prostate cancer and to reduce overtreatment. Furthermore, new definitions for inclusion for *Active Surveillance* follow-up are necessary with this new imaging modality. This study aims to make a full comparison between random biopsies versus MRI-ultrasound targeted biopsies in respect of inclusion for Active Surveillance but also number of prostate cancers diagnosed.

Hypothesis:

MRI-ultrasound fusion biopsies will detect more clinically relevant tumours (I.e. higher Gleason score) when compared to random biopsies.

References:

1) JAMA. 2015;313(4):390-7

2) Curr Opin Urol. 2013;23(1):43-50

3) Eur Urol. 2012;62(5):902-9

4) World J Urol. 2014;32(4):847-58

Study objective

The objective of this study is to improve the treatment of prostate cancer. By more accurately diagnosing both clinically significant and insignificant prostate cancer, treatment strategies will improve. This accounts for active treatment like radical prostatectomy (less understaging) but alsof for Active Surveillance (less overtreatment). Furthermore, this study aims to lower patients' burden by ultimatly reducing the number of biopsies needed.

Researchquestions:

Can random prostate biopsies be safely replaced by MRI-ultrasound fusion biopsies without missing cancers that according to the current definition of Active Surveillance need active treatment?

Will MRI-ultrasound fusion prostate biopsies detect clinically relevant

prostate cancers that demand active treatment and would otherwise be included in Active Surveillance according to random biopsies alone?

Can MRI-ultrasound fusion prostate biopsies reduce the amount of false Active Surveillance follow-up?

Can MRI-ultrasound fusion prostate biopsies improve the amount of true Active Surveillance follow-up?

Will MRI-ultrasound fusion prostate biopsies reduce the amount of patients' burden in both diagnosing (less biopsies) and treatment (less overtreatment)?

Study design

We will perform a observational diagnostic study in which two different methods for taking prostate biopsies within the same patient will be compared.

Inclusion and MRI
Patients, referred for prostate biopsies, will be informed by their urologist about the study. If the urologist together witht the patient decides that the patient will undergo prostate biopsies and the patient is included in the study, the patient will undergo prostate biopsies within 14 days. Before the biopsies a mpMRI will be made. A dedicated UG-radiologist will look at the MRI-scan and draw Regions of Interest (ROIs) if prostate cancer is suspected (PIRADS ((Prostate Imaging Reporting and Data System)) >2).

Biopsies
Patients will undergo 10 standardized ultrasound guided biopsies, 5 biopsies on each side. Each biopsy will be marked with an ink color before it is enclosed in a formaline-filled jar. This way, the specific location of each biopsy is known for the investigator by its color. In the same session, the mpMRI will be fused with the ultrasound images so that two additional biopsies can be taken from the ROI. If no ROI is drawn by the radiologist two random additional biopsies will be taken. These biopsies will also be marked with ink and each enclosed in one of the two jars (left or right side prostate). Each jar will contain 6 biopsies with 6 different colors, linked to a specific location or ROI only known by the investigator.

Pathological examination
The two jars with the marked biopsies will be analyzed and examined by a pathologist who is blind for the color marking. Each biopsy will receive a Gleason score if applicable. Any positive biopsies will be named together with their color so that the investigator can link the biopsy to a specific location.

Revision
The results of the mpMRI and biopsies will be reported to the patient by their own urologist. All biopsies will be used for therapy decision making and

therefore this study can benefit the diagnosis of the participating patient as well.

Study burden and risks

Both MRI-ultrasound fusion biopsies as well as random biopsies will be taken in the same session without removal of the rectal probe. Two additional biopsies will be taken, thereby reducing patients' risk and burden.

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

- Age>18 years,

- Indication for undergoing prostate biopsies
- Written informed consent

Exclusion criteria

- Patients who are suspected in advance to have bone metastases
- Patient not able to undergo MRI

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):	26-01-2018
Enrollment:	350
Type:	Actual

Ethics review

Approved WMO Date:	19-12-2017
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	13-02-2018

Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	27-09-2018
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)

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	NL63640.075.17