ProMES study (prostate biopsies using MR-Ultrasound fusion study).

No registrations found.

Ethical review	Positive opinion
Status	Other
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28981

Source
NTR

Brief title
ProMES study

Health condition

MRI-ultrasound fusion biopsies
Prostate cancer
Prostate biopsies
Targeted biopsies

MRI-Echo fusiebiopten
Prostaatkanker
Prostaatbiopten

Intervention

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, falsenegative

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.

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

same patient will be compared, namely standardized ultrasound guided biopsies and MRI-ultrasound fusion biopsies.

Study objective

MRI-ultrasound fusion biopsies of the prostate will detect more clinically relevant tumours

(I.e. higher Gleason score) when compared to random ultrasound-guided biopsies in the primary prostate biopsy setting.

Study design

1. Intake and informed consent

2. mpMRI of the prostate

3. Prostate biopsies

4. Revision and therapy decision making. After the biopsies, patients will receive standard of care depending on pathology results and are no longer part of the study.

Intervention

We will perform a observational diagnostic study in which two different methods for taking prostate biopsies within the
same patient will be compared, namely standardized ultrasound guided biopsies and MRI-ultrasound fusion biopsies.
Patients will undergo 10 standardized ultrasound guided biopsies, 5 biopsies on each side.

After this, 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.
If two or more ROI's are drawn, a maximum of 4 additional biopsies is taken from the two regions with the highest Gleason score.
MRI-ultrasound fusion biopsies and random biopsies will be taken in the same session without removal of
the rectal probe.

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Eligibility criteria

Inclusion criteria

- Age>18 years

- Indication for undergoing prostate biopsies for the first time

- Written informed consent

Exclusion criteria

- Patients who are suspected in advance to have bone metastases

- Patient not able to undergo MRI

- Former prostate biopsies

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	01-02-2018
Enrollment:	350
Type:	Unknown

Ethics review

Positive opinion

Date:	19-01-2018
Application type:	First submission

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
NTR-new	NL7019
NTR-old	NTR7217
Other	: METC code 171122

Study results