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

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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.

Ethische beoordeling	Positief advies
Status	Anders
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28981

Bron
NTR

Verkorte titel
ProMES study

Aandoening

MRI-ultrasound fusion biopsies
Prostate cancer
Prostate biopsies
Targeted biopsies

MRI-Echo fusiebiopten
Prostaatkanker
Prostaatbiopten

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

All found prostate cancers.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Age>18 years

- Indication for undergoing prostate biopsies for the first time

- Written informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Patients who are suspected in advance to have bone metastases

- Patient not able to undergo MRI

- Former prostate biopsies

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Anders
(Verwachte) startdatum:	01-02-2018
Aantal proefpersonen:	350

Type: Onbekend

Ethische beoordeling

Positief advies
Datum: 19-01-2018
Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7019
NTR-old	NTR7217
Ander register	: METC code 171122

Resultaten