

Navigo™ MR-ultrasound fusion guided biopsies

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We hypothesize that MRI guided targeted prostate biopsies are equal in finding prostate cancer as systematic biopsies, and even better at finding clinical relevant prostate cancer (>Gleason 6).

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27074

Bron

NTR

Aandoening

prostate cancer

Ondersteuning

Primaire sponsor: Department of Urology

Jeroen Bosch Hospital

's-Hertogenbosch

Overige ondersteuning: Astellas Research Grant

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Cancer detection rates

Toelichting onderzoek

Achtergrond van het onderzoek

Despite limitations considering the presence, staging and aggressiveness of prostate cancer, ultrasonography (US)-guided systematic biopsies (SB) are still the 'golden standard' for the diagnosis of prostate cancer. Recently, promising results have been published for targeted prostate biopsies (TB) using magnetic resonance imaging (MRI) and ultrasonography (MRI/US)-fusion platforms. With help of image fusion we are able to navigate the ultrasound guided biopsies to the region of interest (ROI) found on MRI. This may lead to better and quicker diagnosis of prostate cancer. Furthermore there will be less delay in definitive treatment of people who are diagnosed with prostate cancer earlier. Possibly a more accurate Gleason grading can be obtained resulting in more accurate work-up and leading to a more tailored treatment advise.

Doel van het onderzoek

We hypothesize that MRI guided targeted prostate biopsies are equal in finding prostate cancer as systematic biopsies, and even better at finding clinical relevant prostate cancer (>Gleason 6).

Onderzoeksopzet

Both interventions will take place on the same day, in the same biopsy session.

Onderzoeksproduct en/of interventie

In-patient control study.

Patients receive both interventions:

- conventional Navigo™-based systematic biopsies (12 cores)
- in case of region of interest on mpMRI: MR-US fusion targeted biopsies (max 4 cores)

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Men with clinical suspicion for prostate cancer due to PSA >4 ug/L

Age 50-70 years

Biopsy naive

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

PSA >30 ug/L

Contra indications for MR

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	26-01-2016
Aantal proefpersonen:	90
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	16-02-2016
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 43620
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5014

Register

NTR-old

CCMO

OMON

ID

NTR5787

NL51982.028.15

NL-OMON43620

Resultaten