FUTURE trial; A multicentre randomised controlled trial on three target biopsy techniques in the diagnostic work-up of prostate cancer

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

Samenvatting

ID

NL-OMON28778

Bron
Nationaal Trial Register

Verkorte titel
FUTURE trial

Aandoening

Prostate cancer

Ondersteuning

Primaire sponsor: St Antonius Hospital Nieuwegein
Canisius Wilhelmina Hospital Nijmegen
Radboud University Medical Center Nijmegen
University Medical Center Utrecht
Overige ondersteuning: Self-financing

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

To evaluate the clinical role (i.e. detection of significant prostate cancer) of MRI/TRUS fusion target biopsy on prostate cancer detection, compared with in-bore MRI target biopsy and cognitive TRUS target biopsy, in men with a persistent clinical suspicion on prostate cancer and at least one negative TRUS guided biopsy session.

Toelichting onderzoek

Achtergrond van het onderzoek

Three-arm randomised controlled, multicentre trial.
All subjects will undergo 3-T mpMRI (T2W, DCE and DWI) imaging of the prostate. Image acquisition will be according to the detection protocol of ESUR guidelines of prostate imaging. MRI images will be evaluated by an experienced urogenital radiologists by applying central review. Images will be evaluated using the PI-RADS scoring system.
If mpMRI images do not show abnormalities suspicious for tumour (PI-RADS≤2) subjects will enter a biochemical follow-up course of at least 2 years, when discharge may follow. After 2 years contact will be made by telephone to determine whether diagnosis prostate cancer has been made at that interval, and to evaluate what type of diagnostics and/or treatment subjects have undergone with respect to prostate cancer or benign prostate hyperplasia.
If images do show abnormalities suspicious for tumour (PI-RADS>2), subjects will be randomised to undergo one of three target biopsy strategies; MRI/TRUS fusion targeted biopsy (study intervention), in-bore MRI target biopsy (reference standard) or cognitive TRUS target biopsy (current standard of practise). The primary outcome will be tumour detection.

Doel van het onderzoek

This project will result in a different approach to prostate cancer diagnosis. Our hypothesis is that MRI is a crucial factor in patient selection for subsequent target biopsy procedures. Patients with abnormalities on imaging will demonstrate high detection rates of intermediate- and high-grade cancer and follow-up of patients without abnormalities will demonstrate low detection rates.
We expect that the outcome of the study will provide guidelines on how MRI detected cancers should be biopsied. Potentially MRI/TRUS fusion biopsy will be the preferred target biopsy procedure in most lesions, as we expect to demonstrates similar detection rates using MRI/TRUS fusion compared to in-bore MRI target biopsy, and simultaneously demonstrates an increased detection compared to ‘cognitive’ TRUS target biopsy.

Onderzoeksopzet

Our estimations are that we will need approximately 18 months for inclusion to be complete.

Onderzoeksproduct en/of interventie

All subjects will undergo mpMRI imaging according to the ESUR guidelines.

Following mpMRI imaging, subjects with tumor suspicious laesions (PI-RADS >2) will be randomised to undergo one of three target biopsy procedures, namely;

- MRI/TRUS fusion target biopsy

- Cognitive TRUS target biopsy

- In-bore MRI target biopsy

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Subjects (at least 18 years old and mentally competent) with at least one negative TRUS guided biopsy session within the last 2 years (with a minimum of 8 biopsy cores taken from the peripheral zone) but a persistent clinical suspicion on prostate cancer based on a PSA value of >4.0 ng/ml and/or suspicious rectal examination are candidates for recruitment.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Exclusion criteria are prior diagnosed or treated prostate cancer, a urinary tract infection, unwillingness or inability to undergo MR imaging and/or target biopsy session, or follow-up.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-12-2014
Aantal proefpersonen:	674
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	03-12-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 44521
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4870
NTR-old	NTR4988
CCMO	NL48777.100.14
OMON	NL-OMON44521

Resultaten