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

No registrations found.

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

Summary

ID

NL-OMON28778

Source
Nationaal Trial Register

Brief title
FUTURE trial

Health condition

Prostate cancer

Sponsors and support

Primary sponsor: St Antonius Hospital Nieuwegein
Canisius Wilhelmina Hospital Nijmegen
Radboud University Medical Center Nijmegen
University Medical Center Utrecht
Source(s) of monetary or material Support: Self-financing

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

To perform histopathological validation of mpMRI imaging and PI-RADS classification system using target biopsy cores.

To perform histopathological validation of Computer Aided Diagnosis algorithms (Watson Elementary) within the fusion groups of subjects undergoing prostatectomy following biopsy procedures using prostatectomy specimens.

To analyse cost-effectiveness of all three target biopsy strategies.

To evaluate the follow-up amongst subjects with a negative mpMRI and/or negative target biopsy outcome

Study description

Background summary

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.

Study objective

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.

Study design

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

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-12-2014
Enrollment:	674
Type:	Anticipated

Ethics review

Positive opinion

Date:	03-12-2014
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 44521
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

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

Study results