Fusion target biopsy of the prostate using real-time ultrasound and MR images

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To evaluate the clinical role of MRI/TRUS fusion target biopsy on prostate cancer detection, compared with other target biopsy strategies, in men with a persistent clinical suspicion on prostate cancer and at least one negative TRUS guided biopsy…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Renal and urinary tract neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON44521

Source
ToetsingOnline

Brief title
FUTURE Trial

Condition

- Renal and urinary tract neoplasms malignant and unspecified

Synonym
Prostate cancer; malignancy of the prostate; prostate carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: Astellas Pharma,St Antonius onderzoeksfonds; St Antonius Innovatie fonds; maatschap urologie St Antonius Ziekenhuis;

maatschap urologie Canisius Wilhelmina Ziekenhuis; particuliere donatie. Eventueel ZonMw en KWF (subsidie aanvragen ingediend).

Intervention

Keyword: Image fusion, Image guided biopsy, Prostate cancer, RCT

Outcome measures

Primary outcome

Biopsy cores containing prostate cancer; Gleason score in biopsy cores; number

of systematic and target biopsy cores taken.

Secondary outcome

Occurrence of adverse effects; treatment of adverse effect; duration of biopsy

procedure;

number of mpMRI suspicious lesions; PI-RADS score of lesions; imaging staging;

pathological staging (if prostatectomy follows); imaging

modalities/applications used;

Baseline characteristics (PSA value; prostate volume; age of subjects; number

of previous negative biopsy sessions)

Questionnaire scores (EQ5D5L/IPSS/SHIM)

Study description

Background summary

Prostate cancer is the most common malignancy amongst men in the Netherlands, with an incidence of 11.428 in 2011.
Transrectal ultrasound (TRUS) guided biopsy has a low sensitivity and specificity for prostate cancer detection, due to the inability of grey-scale ultrasonography to distinguish prostate cancer from benign prostate tissue.
Repeat biopsies after negative biopsy result show a high incidence of prostate cancer. Consequently a delay of correct diagnosis and treatment occurs.

Development of new MRI techniques have boosted the sensitivity of imaging and increased prostate cancer detection rates. Especially the development op multiparametric (mp) MRI, which includes functional MRI techniques, has contributed to this advancement. International guidelines recommend making a mpMRI if biopsy results are negative but the clinical suspicion on prostate cancer persists. The evaluation of mpMRI is complex and requires expertise by the evaluating radiologist. A standardised method to evaluate mpMRI of the prostate is by applying the PI-RADS classification system. Abnormalities on mpMRI are evaluated using various modalities and graded on a scale of 1 to 5. The higher the PI-RADS score, the higher the chance of malignancy.
Image guided biopsies are promising; a higher percentage pf significant prostate cancer is found, using less biopsy cores. Nevertheless this technique remains controversial due to impracticalities, such as low availability in the Netherlands, and its time consuming and costly nature.
Recently fusion devices have been developed, combining the high sensitivity of MRI for prostate cancer with the practicality of ultrasonography. Studies using these devices show a increase in prostate cancer detection, using less biopsy cores without the necessity to perform the biopsy procedure in the MRI suite. Up to date no multicenter, randomised controlled studies have been executed.

Study objective

To evaluate the clinical role of MRI/TRUS fusion target biopsy on prostate cancer detection, compared with other target biopsy strategies, in men with a persistent clinical suspicion on prostate cancer and at least one negative TRUS guided biopsy session.

Histopathological validation of mpMRI imaging and PI-RADS classification system.

Study design

Three-arm randomised controlled, multicentre trial with 2 sub-investigations.

Sub-investigation 1 consists of superiority study (fusion biopsy vs cognitive biopsy) to demonstrate superiority of the study intervention compared to the currently most applied technique.
Sub-investigation 2 consists of an equivalence study (fusion biopsy vs MRI biopsy) to demonstrate non-inferiority of the intervention compared to the currently best available technique.

Intervention

Study intervention:
MRI/TRUS fusion target perineal prostate biopsy

Comparator interventions:
Cognitive TRUS target prostate biopsy
In-bore MRI target transrectal prostate biopsy

Study burden and risks

The nature and extent of burden associated with participation consists of 2 visits to the out-patient urology clinic, filling in three questionnaires twice; undergoing MRI imaging of the prostate; and possibly undergoing a target biopsy session of the prostate. An estimated 250 minutes per subject is necessary to comlete participation of this investigation. (standard diagnostics)
Risks of participation are ascribed to the undergoing of a target biopsy session. Previously described physical risks include transient haematuria, (febrile) urine tract infection, (exaggeration of) erectile dysfunction, urinary retention, (exaggeration of) lower urinary tract symptoms, perineal hematoma and for the comparator interventions also rectal bleeding.
Based on the currently available publications on target biopsy of the prostate the risk of complications is estimated to be low.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

-At least 18 years old and mentally competent
-At least one negative TRUS guided biopsy session (no cancer diagnosis) within the last 4 years
-A PSA value of >4.0 ng/ml and/or suspicious rectal examination

Exclusion criteria

-Prior diagnosed or treated prostate cancer
-Proven urinary tract infection
-Unwillingness/inability to undergo MRI imaging
-Unwillingness/inability to undergo target biopsy session
-Unwillingness to undergo biochemical follow-up
-Prior target biopsy procedures of the prostate based on MR imaging

Study design

Design

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

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	01-12-2014
Enrollment:	674
Type:	Actual

Ethics review

Approved WMO Date:	19-11-2014
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	07-04-2015
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	18-02-2016
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 28778
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL48777.100.14
OMON	NL-OMON28778